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**UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF CALIFORNIA**

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| HEALTH CARE SERVICE CORPORATION,<br><br>Plaintiff,<br><br>vs.<br><br>JAZZ PHARMACEUTICALS, INC.; JAZZ PHARMACEUTICALS IRELAND LIMITED; JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY; HIKMA PHARMACEUTICALS PLC; HIKMA PHARMACEUTICALS USA INC.; HIKMA LABS, INC.; EUROHEALTH (USA), INC.; AMNEAL PHARMACEUTICALS LLC; PAR PHARMACEUTICAL, INC.; LUPIN LTD.; LUPIN PHARMACEUTICALS INC.; LUPIN INC.,<br><br>Defendants. | Case No.<br><br>COMPLAINT<br><br>JURY TRIAL DEMANDED |

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1. Plaintiff Health Care Service Corporation a Mutual Legal Reserve Company ("HCSC" or "Plaintiff") brings this action against Defendants Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals Ireland Limited, Jazz Pharmaceuticals Public Limited Company, Hikma Pharmaceuticals plc, Hikma Pharmaceuticals USA Inc., Hikma Labs, Inc., Eurohealth (USA), Inc., Amneal Pharmaceuticals LLC, Par Pharmaceutical, Inc., Lupin Ltd., Lupin Pharmaceuticals Inc., and Lupin Inc., (collectively, "Defendants") for violations of antitrust, consumer protection, and common laws. Plaintiff's claims center on Defendants' scheme to restrain competition for branded Xyrem and its AB-rated generic bioequivalents in the United States. Defendants, the brand manufacturer of Xyrem and several putative competitors, abused the patent laws by allocating the market for sodium oxybate, a drug that was discovered nearly 150 years. Sodium oxybate, sold under the brand name Xyrem (also known as γ-hydroxybutyric acid ("GHB")) is a naturally occurring substance found in the central nervous system. Xyrem is manufactured by Jazz Pharmaceuticals, Inc and its affiliates ("Jazz"). Xyrem has historically been Jazz's main source of revenue, making up 70% or more of its revenues since 2007. Jazz's growth and profits have been entirely linked to its ability to increase prices on Xyrem and keep the market to itself. To prevent generic competition and unlawfully maintain this monopoly, Jazz: (1) first, manipulated an FDA safety program meant to mitigate safety risks of certain drugs ("REMS"); (2) second, engaged in sham patent litigation; (3) third, abused the REMS process to further frustrate generic competitors; and (4) forth, agreed with other Defendants to delay generic entry in exchange for allocating the generic market for AB-rated generic Xyrem. All the while, Jazz imposed a series of gobsmacking price hikes that would not have been possible without its brazen antitrust violations. This scheme caused HCSC to pay inflated prices for Xyrem from July 17, 2017 through the present and continuing until the anticompetitive effects of the Defendants' unlawful conduct cease.

## I. INTRODUCTION

2. This litigation challenges a comprehensive anticompetitive scheme to suppress generic competition for Xyrem, a leading narcolepsy treatment. Defendants abused an FDA drug safety program called "Risk Evaluation and Mitigation Strategy," engaged in sham patent litigation, and entered into reverse payments to generic manufacturers to preserve their monopoly in Xyrem. Through this

scheme Defendants suppressed generic competition and raised the price of Xyrem 841% between 2007 and 2014. HCSC and other drug purchasers were the targets of, and footed the bill for, this manipulation.

3. Sodium oxybate, Xyrem's active ingredient in, is a central nervous system depressant that has been widely available in the United States since the 1960s. Sodium oxybate is the chemically derived version of γ-Hydroxybutyric acid (GHB), which occurs naturally in human bodies' central nervous systems, as well as in wine, beef, small citrus fruits, and nearly all animals.[1]

4. Narcolepsy is a disorder characterized by excessive daytime sleepiness ("EDS") and intermittent manifestations of REM sleep during wakefulness. In 1994, the Food and Drug Administration's ("FDA") Orphan Products Development Division and a non-profit advocacy organization approached a small Minnesota-based drug company, Orphan Medical, to instigate the development of sodium oxybate for treatment of cataplexy, a common symptom of narcolepsy where a patient has sudden episodes of bilateral skeletal muscle weakness induced by an emotional trigger such as laughter, anger, embarrassment, or surprise.

5. Orphan Medical began development of what would become Xyrem. In 2002, Orphan Medical secured FDA approval to market sodium oxybate for the treatment of cataplexy associated with narcolepsy in adults. Orphan Medical branded its product Xyrem. In 2005, Orphan Medical obtained FDA approval to market Xyrem for a second indication—EDS, associated with narcolepsy in adults. Until 2021, Xyrem was the only drug that the FDA approved to treat both EDS and cataplexy associated with narcolepsy. In 2020, the FDA also approved Jazz's follow-on sodium oxybate product, Xywav, for the treatment of those conditions.

6. Jazz Pharmaceuticals, Inc. acquired Orphan Medical in 2005. "The acquisition was unprofitable at first . . . . By 2009, Jazz was on the verge of bankruptcy . . . . Jazz responded by replacing

[1] "Gamma-hydroxybutyric acid (GHB), Critical Review Report," World Health Organization Expert Committee on Drug Dependence (2012), found at https://www.who.int/medicines/areas/quality_safety/4.1GHBcritical_review.pdf.

its management team."[2] Jazz then began a series of astronomical price hikes. In May of 2014, Bloomberg published a ranking of drug price increases from 2007 to 2014. Xyrem ranked first with an overall increase of 841% from 2007 to 2014, well-ahead of notorious products such as EpiPen.[3] Overall, from 2007 to the present, the price of Xyrem has increased from about $2/ml to over $31/ml, nearly a 1000% increase.

7. Jazz could only impose these noxious price hikes on HCSC and other parties responsible for managing health care costs because it unlawfully maintained its monopoly in Xyrem. As Jazz's CEO admitted at a 2011 investor conference, Jazz's monopoly was central to its value proposition: "There's really no competition. The other drugs used to treat narcolepsy for the excessive daytime sleepiness part of narcolepsy are stimulants. Those can and are used together with Xyrem, so that's not an 'either/or', it's an 'and' proposition. Probably 80% to 90% of our patients and the patients in our clinical trials were also on stimulants."[4]

8. To maintain its Xyrem monopoly, Jazz installed a series of anticompetitive measures directed at ensuring there would be "no competition" from AB-rated generic Xyrem, the only product that could reign in Jazz's ability to profitably inflate prices.

9. Jazz's scheme "had three main parts that operated in roughly chronological but overlapping order: (a) abuse of an FDA drug safety program called 'Risk Evaluation and Mitigation Strategy'; (b) sham litigation; and (c) reverse payments to four of the generic manufacturers."[5]

10. The capstone to Jazz's scheme began to be instituted in 2017, when it agreed with perhaps its strongest potential competitor, Hikma, to delay generic entry in exchange for a promise by Jazz to not launch an authorized generic. This "no AG" agreement—hidden from the market—ensured Jazz would see no serious generic competition until July 2023: "on April 5, 2017, after nearly seven years of trying to bring an AB-rated generic to market, Hikma agreed to buy and relabel Xyrem rather than

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[2] Order at 2, *In re Xyrem Antitrust Litig.*, Case No. 5:20-md-02966-LHK, (N.D. Cal. Aug. 13, 2021), ECF No. 138 ("Xyrem Order").

[3] "Drug Prices Soar for Top-Selling Brands," Bloomberg, May 1, 2014, *available at* https://www.bloomberg.com/graphics/infographics/drug-prices-soar-for-top-selling-brands.html.

[4] Conference Call Transcript; Jazz Pharmaceuticals, Inc. at Piper Jaffray Health Care Conference, Jazz Pharmaceuticals (Nov. 30. 2011), found at https://investor.jazzpharma.com/node/12191/html.

[5] Xyrem Order at 8.

manufacture a generic version of Xyrem. By agreeing to this, Hikma delayed its allegedly impending entry into Jazz's market over six years until at least July 1, 2023 (i.e., the end of the six-month term for Hikma's AG)."[6]

11. HCSC seeks damages for the overcharges it paid as a result of Defendants' conduct as well as injunctive relief to prevent the Defendants from continuing their unlawful agreements.

## II. JURISDICTION AND VENUE

12. As this is an action asserting claims under Sections 1 and 2 of the Sherman Act, 28 U.S.C. §§ 1 and 2, this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a), and 15 U.S.C. § 15.

13. The Court has subject-matter jurisdiction over the state-law claims alleged in this action pursuant to 28 U.S.C. § 1367, as the state law claims are factually and legally related to the federal claims such that they form part of the same "case or controversy." Similar state law claims are pending in this District in *In re Xyrem Antitrust Litig.*, Case No. 5:20-md-02966-LHK, and thus exercising subject-matter jurisdiction avoids unnecessary duplicity or multiplicity of actions. Supplemental or pendant jurisdiction should be exercised in the interest of judicial economy, and to avoid both duplicative litigation and inconsistent results.

14. Venue is appropriate in this District under 28 U.S.C. §1391 because the claims alleged in this action accrued in this District, the Defendants regularly transact business within this District, have maintained business offices in this District, and have directed their conduct towards HCSC and others from this District.

15. Each Defendant has transacted business, maintained substantial contacts, or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including in this District. The scheme and conspiracy have been directed towards persons and businesses residing in, located in, or doing business throughout, the United States, including in this District.

[6] *Id.* at 29.

## III. THE PARTIES

16. Plaintiff Health Care Service Corporation, a Mutual Legal Reserve Company ("HCSC") is the nation's largest customer-owned health insurer and the fourth largest U.S. health insurer overall, with more than 16 million members. It is organized as a Mutual Legal Reserve Company under Illinois law and is an independent licensee of the Blue Cross and Blue Shield Association ("BCBSA"). Through its operating divisions, HCSC has an exclusive license to offer BCBSA-branded health plans in Illinois, Montana, New Mexico, Oklahoma, and Texas. Through its operating divisions and subsidiaries, it also offers other health plans and health-related services. In particular, HCSC offers "Administrative Services Only" ("ASO") services to self-funded health plans across the United States. HCSC is headquartered at 300 E. Randolph Street, Chicago, Illinois.

17. HCSC, through its operating divisions and subsidiaries, provides, *inter alia*: (1) Medicare benefits through contracts with the Centers for Medicare and Medicaid Services ("CMS") for Medicare beneficiaries through a variety of Medicare Advantage plans offered under Part C of Medicare, and prescription drug benefits under Part D of Medicare; (2) benefits under various states' Medicaid programs; and (3) private commercial health insurance plan benefits that cover the medical expenses incurred by plan beneficiaries on an individual or group basis. These benefits include prescription drug coverage under which claims for Xyrem were submitted and paid.

18. Through its operating divisions HCSC also administers health plan benefits for its members and group customers, including self-funded customers that contract with HCSC to administer health insurance benefits on their behalf and pursue recoveries related to those claims. Many of these health plan benefits provide members with prescription drug coverage under which claims for Xyrem were submitted and paid. HCSC is also pursuing recovery related to those claims.

19. Defendant Jazz Pharmaceuticals, Inc. is a corporation organized under the laws of the State of Delaware, with its principal place of business at Waterloo Exchange, Waterloo Road, Dublin 4, Ireland. Its U.S. headquarters is located at 3170 Porter Drive, Palo Alto, CA 94304 and it maintains other offices in Philadelphia, Pennsylvania and Ewing, New Jersey. Jazz principally develops, manufactures, and markets brand name drugs.

20. Defendant Jazz Pharmaceuticals Ireland Limited is a corporation organized under the laws of Ireland, with its principal place of business at Waterloo Exchange, Waterloo Road, Dublin 4, Ireland.

21. Defendant Jazz Pharmaceuticals Public Limited Company is an Ireland public limited biopharmaceutical company organized under the laws of Ireland, with its principal place of business at Waterloo Exchange, Waterloo Road, Dublin 4, Ireland. Jazz Pharmaceuticals plc's common stock is publicly traded in the United States on the NASDAQ stock exchange. Jazz Pharmaceuticals plc is the parent company of Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited.

22. Each of the three Jazz Defendants (collectively, "Jazz") was directly and substantially involved in the planning and execution of the anticompetitive acts alleged herein. Among other things, Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited were parties to the document styled as the "Settlement Agreement" in this complaint. Jazz Pharmaceuticals plc was directly involved in the negotiation of the unlawful agreements described in this complaint.

23. Jazz manufactures and sells Xyrem, the only FDA-approved product for the treatment of both cataplexy and excessive daytime sleepiness ("EDS") in both adult and pediatric patients with narcolepsy.

24. Defendant Hikma Pharmaceuticals plc is a public limited company organized under the laws of the United Kingdom, with its principal place of business at 1 New Burlington Place, London, W1S 2HR and its U.S. headquarters are loctaed 246 Industrial Way West, Eatontown, New Jersey 07724.

25. Defendant Hikma Pharmaceuticals USA Inc. is a corporation organized under the laws of the State of Delaware, with its principal place of business also located at 246 Industrial Way West, Eatontown, New Jersey 07724. Hikma Pharmaceuticals USA Inc. is a wholly owned subsidiary of Hikma plc. Before June 20, 2018, Hikma Pharmaceuticals USA Inc. was organized under the name West-Ward Pharmaceuticals Corp., which had been acquired by Hikma Pharmaceuticals plc in 1998.

26. Defendant Hikma Labs, Inc. is a corporation organized under the laws of the State of Nevada, with its principal place of business at 1809 Wilson Road, Columbus, Ohio 43328. Hikma Labs,

Inc. was formerly known as Roxane Laboratories, Inc., which was purchased by West-Ward Pharmaceuticals Corp. in 2016 and is now a wholly owned subsidiary of Hikma Pharmaceuticals plc. In June 2018, the company changed its name from Roxane Laboratories, Inc. to Hikma Labs, Inc.

27. Defendant Eurohealth (USA), Inc. is a holding company for Hikma Pharmaceuticals USA Inc. and a wholly owned subsidiary of Hikma Pharmaceuticals plc. Eurohealth (USA) Inc. is organized under the laws of the State of Delaware, with its principal place of business located at 246 Industrial Way West, Eatontown, New Jersey, 07724.

28. Each of the Hikma-related Defendants was directly and substantially involved in planning, entering into, and performing under the agreements reached beginning in 2017, as alleged in this complaint. Among other things, Roxane Laboratories, Inc., West-Ward Pharmaceuticals Corp., Eurohealth (USA), Inc., and Hikma Pharmaceuticals plc were parties to the document styled as the "Settlement Agreement" in this Complaint.

29. Defendant Amneal Pharmaceuticals LLC is a limited liability company organized under the laws of the State of Delaware, with its principal place of business located at 400 Crossing Boulevard, Bridgewater, New Jersey 08807.

30. Defendant Par Pharmaceutical, Inc. is a corporation organized under the laws of the State of Delaware, with its principal place of business located at One Ram Ridge Rd., Chestnut Ridge, New York 10977. Par is a subsidiary of Endo International plc, an Irish public limited company with its U.S. headquarters located in Malvern, Pennsylvania. In September 2015, Endo acquired Par Pharmaceuticals Holdings, Inc. and its subsidiaries, including Par Pharmaceutical, Inc., and combined it with Endo International plc's existing generics subsidiary, Qualitest Pharmaceuticals. As used in this complaint, "Par" encompasses its relevant predecessors-and-successors-in-interest.

31. Defendant Lupin Ltd. is a public limited company organized under the laws of India, with its principal place of business at B/4 Laxmi Towers, Bandra-Kurla Complex, Bandra (E), Mumbai 400 051, India.

32. Defendant Lupin Pharmaceuticals Inc., a wholly owned subsidiary of Lupin Ltd., is a corporation organized under the laws of the State of Delaware, with its principal place of business at 111 South Calvert Street, Baltimore, Maryland 21202.

33. Defendant Lupin Inc., a wholly owned subsidiary of Lupin Ltd., is a corporation organized under the laws of the State of Delaware, with its principal place of business located at 111 South Calvert Street, Baltimore, Maryland 21202.

34. All of Defendants' wrongful actions described herein are part of, and in furtherance of, the illegal monopolization and restraint of trade alleged herein, and were authorized, ordered, and/or undertaken by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants.

## IV. REGULATORY BACKGROUND

### A. Regulatory approval structure and administration of generic drugs.

#### 1. The regulatory constraints on the prescription drug marketplace.

35. Defendants manipulated the unique features of the prescription drug marketplace, ensuring that their anticompetitive market allocation scheme would reap them the maximum profits to the detriment of purchasers such as HCSC.

36. In the pharmaceutical marketplace, the patient cannot freely select his or her pharmaceuticals as he or she does other, unregulated products.

37. Prescription drugs may only be dispensed under a doctor's prescription. For any given script, a pharmacist may dispense only the brand-name drug named in the prescription or its FDA-approved AB-rated generic bioequivalent.

38. In most instances, the patient and his health insurer pay for the prescription drug that a doctor has prescribed. Like the pharmacist, their "choice" is limited to the brand name drug named in the prescription or its AB-rated generic bioequivalent.

39. The doctor's prescription thus defines the relevant product market, because it limits the purchasers' (and pharmacist's) choice to the product prescribed.

40. When there is no generic competition for a brand name drug, the brand manufacturers can set and maintain prices without losing market share. The ability to do this is the result of the brand name drug company's monopoly power over the market for that drug in both its brand name and generic form.

41. High-cost and overpriced brand name prescription drugs remain among the largest cost drivers in the delivery of healthcare in the U.S. According to Centers for Medicare and Medicaid Services ("CMS") data, U.S. spending on prescription drugs rose from $783 per capita in 2007 to $1,025 per capita in 2017 and is expected to reach $1,635 per capita by 2027.[7] These high costs are primarily borne by health benefit providers such as HCSC.

42. HCSC and other health benefit providers pay for drugs at the point of sale—*e.g.*, the pharmacy counter—and pay for the cost of those drugs less whatever portion is covered by a plan enrollees' copay, coinsurance and/or deductible.[8] As a result, in the aggregate (and particularly for brand name prescription drugs lacking low-cost generic alternatives), HCSC and other health benefit providers often cover the majority of the cost.

**2. The Hatch-Waxman Act and FDA Approval Process.**

43. The Federal Food, Drug and Cosmetics Act (21 U.S.C. §§ 301-392) ("FDCA"), provides that a manufacturer that creates a new drug must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). A drug sponsor must submit extensive (and costly) testing data in the NDA it submits to the FDA which outlines the specific data it contends demonstrates the

[7] *See Why Are Prescription Drug Prices Rising and How do They Affect the U.S. Fiscal Outlook?*, PETER G. PETERSON FOUND. (Nov. 14, 2019), www.pgpf.org/blog/2019/11/why-are-prescription-drug-prices-rising-and-how-do-they-affect-the-us-fiscal-outlook.

[8] Copayment is "[a] fixed amount [consumers] pay for a covered healthcare service, usually when [they] receive the service." Coinsurance, in contrast, is consumers' "share of the costs of a covered healthcare service, calculated as a percentage" and usually applicable after a consumer pays his or her insurance deductible. CMS, *Glossary of Health Coverage and Medical Terms*, *available at* www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/Uniform-Glossary-01-2020.pdf.

safety and efficacy of the drug as measured by clinical trial results. A drug sponsor must also include a specification of any patents it claims covers the drug in the NDA. 21 U.S.C. § 355(b).

44. To encourage substitution of generic drugs, and thereby introduce market competition to alleviate high drug costs, Congress in 1984 amended the FDCA with the enactment of the Hatch-Waxman Act ("Hatch-Waxman"). The Hatch-Waxman Act simplified the process for FDA approval of generic drugs. Hatch Waxman replaced the lengthy and costly NDA approval process with an expedited Abbreviated New Drug Application ("ANDA") process. The new ANDA process was intended to radically reduce the regulatory hurdles for prospective generic manufacturers.[9] Under the Act, an ANDA drug sponsor can rely on the safety and efficacy findings the FDA made in connection with the NDA for the referenced brand-name drug. Instead of repeating these clinical studies, a generic manufacturer needs only to demonstrate in its ANDA that its proposed generic drug is "bioequivalent," (i.e., it contains the same active ingredient(s), dosage form, route of administration, and strength) as the brand-name drug, and is absorbed at the same rate and to the same extent as the brand-name drug.

45. FDA assigns the generic drugs it approves them an "AB" rating. This rating is a declaration from the FDA that the generic drug is a substitute for the reference-listed brand drug in terms of bioequivalence and efficacy.

46. While paving the road for generic competition, Hatch Waxman provided some benefits to brand manufacturers to compensate for the benefits it provided to generic manufacturers. The Act granted the brand-name manufacturer a 30-month stay of generic approval should the branded manufacturer sue a generic company within 45 days of the time it learns of an ADNA filing. This automatic stay has been the subject of repeated abuse by the pharmaceutical industry. Brand manufacturers often file frivolous patent litigation for the sole purpose of unduly delaying generic competition.[10]

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[9] *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[10] *See* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 NEW YORK UNIV. L. REV. 1553 (2006); Rebecca S. Eisenberg & Daniel A. Crane, *Patent Punting: How FDA and Antitrust Courts Undermine the Hatch-Waxman Act to Avoid Dealing with Patents*, 21 MICH. TELECOMM. & TECH. L. REV. 197 (2015); Saami Zain, *Antitrust Liability for Maintaining Baseless Litigation*, 54 SANTA CLARA L. REV. 729 (2014).

47. When the FDA approves a brand-name manufacturer's NDA, it includes notice of the approval in a publication entitled the "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as the "Orange Book"). In addition to the approval, the FDA lists any patents which the drug sponsor contends: (1) claim the approved drug or its approved uses; and (2) can support a "claim of patent infringement . . . if a person is not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1); 21 U.S.C. § 355(g)(7)(A)(iii).

48. To obtain FDA approval of an ANDA, the sponsor must certify that it will infringe no patent listed in the Orange Book claiming the brand-name drug, because either: (1) no patent is listed therein; (2) the listed patents have all expired (a "Paragraph II Certification"); (3) the listed patents will all expire before the ANDA applicant agrees to market its product (a "Paragraph III Certification"); or (4) the listed patents are either invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV Certification").[11] When a generic manufacturer makes a Paragraph IV Certification, it must notify the brand manufacturer and patent owner. The Hatch-Waxman Act considers this certification an artificial act of patent infringement, entitling the patent holder to sue the generic manufacturer.

49. If the patentee sues the ANDA filer within 45 days of receiving a Paragraph IV certification, the FDA may not grant final approval to the ANDA until the earlier of (a) 30 months after the lawsuit is filed, or (b) the court presiding over the infringement action rules that the patent is invalid or not infringed by the ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). Very often the 30-month period expires before the court rules, resulting in a *de facto* 30-month statutory stay.

50. The FDA may grant "tentative approval" to an ANDA applicant if the FDA determines prior to the expiration of the 30-month stay that the ANDA would otherwise qualify for final approval.

51. Hatch-Waxman grants a 180-day period of market exclusivity to the first Paragraph IV ANDA applicant to file a substantially complete ANDA. During the 180-day exclusivity period (measured from the first commercial marketing of the generic drug or the date of a court decision finding the listed patent invalid, unenforceable, or not infringed, 21 U.S.C. § 355(j)(5)(B)(iv)); *see also* 21

[11] 21 U.S.C. § 355(g)(2)(A)(vii).

C.F.R. § 314.107(c)(1)), the first ANDA filer enjoys 180 days of freedom from competition from other generic versions of the drug. This first mover advantage also allows the first filer to capture a substantial portion of the generic market for the drug at higher prices than the market would support once additional generics enter the market.

52. The Supreme Court has recognized that "this 180-day period of exclusivity can prove valuable, possibly 'worth several hundred million dollars' " to the first filer.[12]

53. Prior to 2003, an ANDA "first filer" could manipulate the 180-day exclusivity period to achieve anticompetitive ends. To frustrate and prevent pharmaceutical manufacturers from gaming Hatch Waxman, Congress enacted the Medicare Prescription Drug Improvement and Modernization Act of 2003 (Public Law 108-173; 21 U.S.C. A. § 355(j)(5)(D)) ("MMA"). The MMA created numerous conditions under which a first ANDA filer forfeits its 180-day exclusivity, thereby allowing other ANDA filers to enter the market. For example, forfeiture occurs if the first filer fails to obtain tentative approval within 30 months from filing, unless the failure is caused by a change in, or review of, the approval requirements.

54. Under the "Agreement with another applicant" MMA provision, 21 U.S.C. A. § 355(j)(5)(D)(i)(V), the first ANDA filer forfeits its exclusivity period if it "enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the [Paragraph IV certification]…."

55. Under the "failure to market" MMA provision, 21 U.S.C.A. § 355(j)(5)(D)(i)(I), a first ANDA filer forfeits its 180-day exclusivity if it fails to market its generic drug by the later of: (a) the earlier of (i) 75 days after receiving final FDA approval; or (ii) 30 months after the date it submitted its ANDA; or (b) 75 days after the date as of which, as to each of the patents qualifying the first applicant for exclusivity (i.e., as to each patent for which the first applicant submitted a Paragraph IV certification), at least one of the following has occurred: (i) a final decision of invalidity or non-

[12] *FTC v. Actavis, Inc.*, 570 U.S. 136, 144 (2013) (quoting C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1579 (2006)).

infringement; (ii) a settlement order entering final judgment including a finding the patent is invalid or not infringed; or (iii) the NDA holder delists the patent from the Orange Book.

56. Since the MMA was enacted, branded manufacturers and first ANDA filers have unfortunately structured their "pay-for-delay" settlements to circumvent the "fixes" of the MMA to continue to keep the 180-day exclusivity in place. These work-arounds include, among others, (1) settling litigation before a final judgment of invalidity or non-infringement can be entered; or (2) seeking a consent judgment that does not include a finding that all the patents for which the first filer submitted a Paragraph IV certification were invalid or not infringed. These tactics unduly prolong exclusivity as all subsequent ANDA filers must themselves obtain a judgment that all patents for which the first ANDA filer certified under Paragraph IV certification were invalid or not infringed to trigger forfeiture and allow multisource generic competition.

57. When the FDA approves an ANDA, that generic drug receives an "AB" rating from the FDA, signifying it is bioequivalent to the brand-name drug. Bioequivalence indicates that the generic has no significant difference in the rate and extent of absorption of the active pharmaceutical ingredient to the brand-name drug such that it can be switched by a pharmacist without physician intervention.

58. Typically, AB-rated generic versions of brand-name drugs are priced significantly below their brand-name counterparts. When multiple generic manufacturers enter the market, prices for generic versions of a brand-name drug predictably decrease, sometimes as much as by 90% because of price competition among generic manufacturers. This price drop starts immediately when one generic manufacturer enters the market and quickly accelerates as other manufacturers enter.

59. The FDA reports that in 2010, the use of FDA-approved generics saved $158 billion, or $3 billion per week, and that one year after entry, a generic drug takes over 90% of the corresponding brand-name drug's sales at 15% of the price. Generic drug entry, therefore, is a huge threat to the continued profitability of a branded drug.

60. As the price gap between the branded drug and its corresponding generic drug widens, the branded drug's utilization sinks along with its sales. Price is the only material difference between a brand-name drug and its AB-rated generic equivalent.

61. Due to Hatch-Waxman and the MMA, for every step in the prescription drug sales and distribution system there is a financial benefit in prescribing generic drugs. In the vast majority of circumstances, and particularly with expensive drugs like Xyrem, HCSC saves money by paying for generic drugs instead of their branded equivalents at the pharmacy counter.

62. Pharmacies normally earn a higher markup on generic drugs because of pricing structure and federal reimbursement rules; private health insurers typically offer incentives to pharmacies to fill prescriptions with generics; and to incentivize patients to request generic drugs, health insurers often offer lower copays for generic drugs than for brand-name drugs. A prescription drug may be dispensed in the United States to a patient only by a licensed pharmacist pursuant to a doctor's prescription which identifies the drug, and the prescription may be filled only with the brand name drug identified or an AB-rated generic version of the brand name drug.

63. State law automatic substitution laws, passed since the Hatch-Waxman Amendments, provide further savings to consumers. Every state has adopted drug product selection laws that either require or permit pharmacies to substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician specifically directs that substitution is not permitted). Substitution laws facilitate dramatic price declines and sales shifts from the brand to the generic following the launch of AB-rated generic. Generic competition enables purchasers to buy the same therapy as a branded product at substantially lower prices. However, until generic manufacturers enter the market with an AB-rated generic, there is no bioequivalent generic drug which competes effectively with the brand-name drug, and therefore, the brand-name manufacturer can continue to charge supra-competitive prices without losing sales. Given their acute knowledge of the effects of generic entry into a market, brand-name manufacturers like Jazz are under enormous pressure to delay the entry of a generic drug onto the market by any means available to them, including by striking anticompetitive deals with generic manufacturers and filing frivolous lawsuits, among other tactics.

**3. Use of authorized generics to enhance profits after generic entry.**

64. Rational profit-maximizing brand drug companies sell authorized generics ("AGs") in order to capture part of the competing AB generic drug market following generic entry. AGs compete

on price with AB generic upstarts. "[P]harmaceutical developers facing competition from generics have large incentives to compete with their own or licensed 'authorized generics.' "[13]

65. The AG is chemically identical to the brand drug, as are other AB-rated generic drugs.

66. Brand drug manufacturers generally launch AGs shortly before generic entry to avoid competing with their own brand product during the majority of the time that the branded version is the only therapy available. To facilitate this strategy a brand manufacturer may sell an AG before the first-filed generic manufacturer enters the market so that it can take advantage of existing networks and pipelines prior to the broader entry of generic competition.

67. Competition from a brand's AG leads to lower prices and profits for the first filed generic entrant. Empirical analysis of drug markets show "authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand."[14]

68. It is generally accepted that, as estimated by the FTC, an AG reduces the first-filed generic manufacturer's revenues by about 50% on average. This is due to the lower market share, and the lower prices that prevail when a first-filed generic manufacturer encounters an AG.

69. AGs are pro-competitive because they can result in purchasers like HCSC paying far less for generic drugs. In addition, AG are the only potential source of competition to a first-filed generic during Hatch Waxman's 180-day exclusivity period.

70. When the brand manufacturer's brand product competes against only the first-filer generic manufacturer's product, the two manufacturers enjoy a duopoly. Profit margins remain very high without multisource generic competition. During this period of time, both the brand and the first-filer share a common aim to prevent competition from other generic manufacturers.

71. To preserve the high margins and profits for longer periods of time, brand and generic manufacturers began to agree to "no-AG" provisions. Patent litigation that is settled with "no-AG"

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[13] Kevin A. Hassett & Robert J. Shapiro, *The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals* 3, SONECON (2007), *available at* http://www.sonecon.com/docs/studies/050207_authorizedgenerics.pdf.

[14] Ernst R. Berndt et al., *Authorized Generic Drugs, Price Competition, and Consumers' Welfare*, 26 HEALTH AFFAIRS 790, 796 (2007).

agreements deliver exclusivity and the ability to charge high prices to the generic manufacturer during the 180-day exclusivity period. The agreement to allow future generic entry with a "no-AG" provision in a settlement is therefore tantamount to a large cash payment.

**4. Acceleration clauses serve as a "poison pill" deterring further generic entry.**

72. To enforce an anticompetitive "no AG" agreement, the brand and generic manufacturers at times resort to the use of acceleration clauses in their settlement agreements that deter future generic companies from challenging weak patents. Later-filed generic manufacturers could win a challenge to the patent, or they could negotiate entry in the event the first-filed generic manufacturer loses its exclusivity. To guard their duopoly against these contingencies, brand and generic companies put terms in their settlement agreements that allow the first-filed generics to launch earlier than an otherwise agreed-to date to eliminate the profit motive of the later-filed generics in challenging the branded weak patents.

73. Acceleration clauses such as those described serve as a bottleneck, and a disincentive for other generic companies to come to market.[15] These acceleration clauses operates as a "poison pill" with respect to other potential entrants in the market for generic manufacturing by providing a disincentive to enter the market. There is a disincentive for potential generic entrants because they would have to share the generic market with the first-filed generic manufacturer.

74. These provisions enforce the "pay to delay" provisions by diminishing the value of any opportunity to take advantage of the first-filed generic manufacturer's decision to agree to delay its entry. Most-favored entry clauses can also contain a provision that goes even further and provides that the brand manufacturer will not grant a patent license to any other generic manufacturer to enter the market under the authority of the generic competitor's ANDA until a defined period of time after the first filer enters. The clause may state that the brand manufacturer will not grant a license to any later filer to enter the market until 180 days after the first filer enters.

[15] Keith M. Drake & Thomas G. McGuire, *Generic Entry Before the Agreed-Upon Date in Pharmaceutical Patent Settlements*, 16 J. COMPETITION L. & ECON. 188, 188 (2020).

75. A most favored entry "plus" agreement forecloses the possibility that the brand will license its patents to a second generic manufacturer, which can then enter the market under its own ANDA. Most favored entry "plus" agreements eliminate the ability of later-filed generic manufacturers to negotiate a licensing agreement with a brand manufacturer as part of a settlement, and further disincentivize other generic manufacturers from challenging weak patents.

76. Empirical evidence demonstrates the anticompetitive nature of acceleration clauses. Such "acceleration clauses have never promoted earlier generic entry where, as here, the first-filer (Hikma) has retained its 180-day period of exclusivity."[16] Indeed, in "the 54 cases in which the first filer retained sole rights to the 180-day exclusivity period, there were no cases of early generic entry. In other words, there were no cases in which the first filer's entry was accelerated, and there were no cases in which a different generic entered before the entry date set in the first-filer's settlement."[17]

## V. DEFENDANTS' ANTICOMPETITIVE CONDUCT

### A. Sodium Oxybate's development.

77. Synthesis of the chemical sodium oxybate was first reported in 1874. Beginning in the 1960s, sodium oxybate, under the name GHB,[18] was marketed in the United States as an unregulated dietary supplement in health food stores, gyms, fitness centers, and on the Internet beginning in the 1980s.[19] Sodium oxybate was also the subject of numerous preclinical and clinical studies for treatment of various diseases and conditions, including insomnia.

78. By 1990, GHB had gained notoriety as a substance prone to abuse. Users reported effects of disinhibition similar to that associated with alcohol consumption but without "hangover" effects. An increasing number of people taking GHB experienced overdoses requiring hospital emergency care and many combined GHB with alcohol, producing synergistic CNS depressant effects. GHB was also implicated in an increasing number of drug-facilitated sexual assaults. Like many other

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[16] Xyrem Order at 39.
[17] Drake & McGuire, *supra*, at 194.
[18] *Gamma-hydroxybutyric acid (GHB) Critical Review Report*, World Health Organization Expert Committee on Drug Dependence Thirty-Fifth Meeting, Hammamet, Tunisia, 4-8 June 2012.
[19] David E. Fuller, M.D., and Carl S. Hornfeldt, Ph.D., *From Club Drug to Orphan Drug: Sodium Oxybate (Xyrem) for the Treatment of Cataplexy*, PHARMACOTHERAPY 2003; 23(9): 1205–1209.

CNS depressants, GHB can cause anterograde amnesia, especially when combined with alcohol, leaving an assault victim unable to recall details of the event.

79. In 1990, the FDA warned against—and thereafter banned—consumption of GHB after escalating reports of overdose. Despite the ban on sales, GHB continued to be abused, which eventually resulted in the DEA designating it as a Schedule I controlled substance. This designation threatened to hinder future development of GHB for therapeutic applications. Successful lobbying efforts on behalf of physicians and patients, however, led to modification of the Controlled Substance Act to create a bifurcated schedule for GHB, allowing sodium oxybate to be designated a Schedule III controlled substance for medical purposes while retaining Schedule I penalties for illegal use.

**B. Sodium Oxybate as a narcolepsy treatment.**

80. "The journey for Orphan Medical began in 1994 when the FDA approached the company to gauge its interest in developing GHB as a treatment for narcolepsy. The drug previously had been under development for narcolepsy[.] [Cataplexy] a symptom of the chronic sleep disorder narcolepsy, is an alarming condition, resulting in sudden, brief episodes of muscle weakness or paralysis brought on by strong emotions such as laughter, anger, surprise, or anticipation."[20] At that time, there were no treatments for cataplexy.

81. Studies that date to the 1970s strongly suggested that sodium oxybate could be used to treat narcolepsy.

82. "Narcolepsy is a chronic sleep disorder characterized by overwhelming daytime drowsiness [excessive daytime sleepiness or 'EDS'] and sudden attacks of sleep. People with narcolepsy often find it difficult to stay awake for long periods of time, regardless of the circumstances. Narcolepsy can cause serious disruptions in your daily routine. Sometimes, narcolepsy can be accompanied by a sudden loss of muscle tone (cataplexy), which can be triggered by strong emotion."[21]

83. Narcolepsy is an incurable chronic condition.

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[20] Elisabeth Pena, "Xyrem: Awakenings," PHARMAVOICE (Oct. 2002); *available at* https://www.pharmavoice.com/article/2002-10-xyrem-awakenings/.

[21] MAYO CLINIC, Narcolepsy, *available at* https://www.mayoclinic.org/diseases-conditions/narcolepsy/symptoms-causes/syc-20375497 (last visited Feb. 16, 2022).

84. Jazz banked on the fact that narcolepsy was a chronic condition, and that "90% of insured patients have access" to the drug, and that health insurers overwhelmingly footed the bill for payment for Xyrem.[22]

85. Orphan Medical submitted a new drug application to the FDA. On July 17, 2002, the FDA approved sodium oxybate for the treatment of cataplexy in patients with narcolepsy. The approval provided New Chemical Entity ("NCE") exclusivity through July 17, 2007. The FDA extended the exclusivity period to July 17, 2009 when it designated Xyrem as an orphan drug because it treated a rare disease.

86. Orphan Medical branded the product Xyrem. Xyrem is an oral solution that is recommended to be taken twice a night, the first dose at bedtime and the second dose two-and-a-half to four hours later.

87. Because of concerns about the risk of drug diversion, Orphan Medical collaborated with the FDA, experts in drug abuse prevention, and clinicians to create the Xyrem Risk Management Program, known as "RiskMAP." The program's goals were to ensure responsible distribution of Xyrem to patients with narcolepsy and to provide education to physicians and patients about safe and responsible administration of the drug. Components of the original plan included: (a) a single, centralized pharmacy housed in a secure facility; (b) a program to educate physicians and patients about the risks and benefits of Xyrem; (c) requiring prescribers and patients to read educational materials before filling an initial prescription; and (d) maintenance of a registry of all patients and a record of all prescribers.

88. Xyrem was and is exclusively dispensed by Express Scripts Specialty Distribution Services, Inc. ("ESSDS"), the only pharmacy authorized under the REMS program to distribute Xyrem. The centralized pharmacy maintained comprehensive patient and physician registries and verified the eligibility of prescribing physicians before filling Xyrem prescriptions. In addition, pharmacists were trained to be alert for compliance issues and suspicious behavior. Under the RiskMap program, Orphan owned the inventory and the centralized pharmacy maintained it on consignment. From the date of its

[22] Jazz Pharmaceuticals plc, SEC Form 425 (filed 9/20/2011).

FDA approval, Jazz has dispensed Xyrem directly to patients under the RiskMAP and REMS through ESSDS.

89. ESSDS ships and distributes Xyrem directly to HCSC's members.

**C. Jazz acquires Orphan Medical and thereby the rights to Xyrem.**

90. In April 2005, Jazz Pharmaceuticals, then a small privately-held drug company formed in 2003, announced plans to acquire Orphan Medical (and thereby all rights to Xyrem) in a leveraged acquisition.[23] Xyrem has since been Jazz's main source of revenue, contributing up to 75% (or more) thereof.

91. The FDA approved Xyrem for the treatment of EDS in adult patients with narcolepsy in October 2005. EDS is the most common and disabling symptom of narcolepsy and is present in all patients with the disease.

92. After approval, the FDA granted Xyrem an NCE exclusivity of five years from the NDA approval date, expiring on July 17, 2007, and orphan drug exclusivity of seven years from the NDA approval date, expiring on July 17, 2009. These exclusivity grants meant that Xyrem would not face competition from generic competitors until at least mid-2009.

**D. The Xyrem patents.**

93. After acquiring Orphan Medical, Jazz filed for and obtained several patents claiming aspects of Xyrem and its use, a delay tactic commonly referred to as "evergreening." According to a Congressional report, evergreening "is the practice of filing for new patents on secondary features of a particular product as earlier patents expire, thereby extending patent exclusivity past the original twenty-year term. Later-filed patents may delay or prevent entry by competitors, thereby allowing the brand-name drug manufacturer (the brand) to continue charging high prices."[24]

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[23] Jazz Pharmaceuticals to Acquire Orphan Medical; Combines Orphan Medical's Growing Central Nervous System Product and Commercial Team with Jazz Pharmaceuticals' Development Pipeline, Orphan Medical Inc., Ex. 99.1 to SEC Form 8-K (filed Apr. 20, 2005).

[24] Kevin T. Richards, Kevin J. Hickey, and Erin H. Ward, "Drug Pricing and Pharmaceutical Patenting Practices," Congressional Research Service (Feb. 11, 2020), at 1, *available at* https://sgp.fas.org/crs/misc/R46221.pdf.

94. Evergreening covers "secondary" aspects of brand drug, such as dosages, method of use, and does not concern active ingredients. Evergreening allows weak secondary patents to unduly delay generic entry: "the combination of secondary patents and a strong primary patent creates a barrier to generic entry because a generic manufacturer may delay or simply decline entry when faced with the prospect of defeating both patents."[25]

95. When Jazz acquired Orphan Medical it obtained a series of secondary patents—the '431 family, the '730 family, and the '302 family—through evergreening.

**1. The '431 patent family (formulations and methods of treatment).**

96. The parent patent for the '431 family of patents is U.S. Patent Application No. 09/470,570 (filed Dec. 22, 1999). Jazz obtained the '431 patents between eight and seventeen years after the parent patent, as part of an "evergreening" strategy to frustrate generic competition. The '431 patents are:

**THE '431 PATENT FAMILY: LISTED IN THE ORANGE BOOK**

| U.S. Patent No. | Application Date | Issue Date | Expiry[26] |
|---|---|---|---|
| 7,262,219 | July 7, 2004 | Aug. 28, 2007 | July 4, 2020 |
| 7,851,506 | July 13, 2007 | Dec. 14, 2010 | Dec. 22, 2019 |
| 8,263,650 | Apr. 13, 2012 | Sept. 11, 2012 | Dec. 22, 2019 |
| 8,324,275 | Apr. 13, 2012 | Dec. 4, 2012 | Dec. 22, 2019 |
| 8,859,619 | Nov. 26, 2012 | Oct. 14, 2014 | Dec. 22, 2019 |
| 8,952,062 | March 6, 2013 | Feb. 10, 2015 | Dec. 22, 2019 |
| 9,539,330 | Nov. 9, 2015 | Nov. 8, 2016 | Dec. 22, 2019 |

97. The '431 patent family concerns formulations of sodium oxybate or other salts of GHB (the '889, '219, '650, '619, and '330 patents); methods of treatment (the '506, '650, '275, and '062 patents); and manufacturing processes (Patent No. 6,472,421, issued on October 22, 2002 and expired

[25] *Id.* at 17.

[26] Expiration dates do not consider pediatric exclusivity extensions. The FDA can grant pediatric exclusivity to extend patents under certain circumstances.

on December 22, 2019, and Patent No. 8,461,203, issued on June 11, 2013 and expired on December 22, 2019, neither of which are listed in the Orange book).[27]

**2. The '730 patent family (drug distribution system and methods).**

98. The parent patent to the '730 family is U.S. Patent Application No. 10/322,348 (filed on December 17, 2002). The Orange book listed '730 family of patents are:[28]

**THE '730 PATENT FAMILY: LISTED IN THE ORANGE BOOK**

| U.S. Patent No. | Application Date | Issue Date | Expiry (w/o pediatric exclusivity) |
|---|---|---|---|
| 7,668,730 | Dec. 17, 2002 | Feb. 23, 2010 | June 16, 2024 |
| 7,765,106 | Nov. 2, 2004 | July 27, 2010 | June 16, 2024 |
| 7,765,107 | Apr. 1, 2005 | July 27, 2010 | June 16, 2024 |
| 7,895,059 | Feb. 11, 2010 | Feb. 22, 2011 | Dec. 17, 2022 |
| 8,457,988 | Aug. 27, 2012 | June 4, 2013 | Dec. 17, 2022 |
| 8,589,182 | Aug. 27, 2012 | Nov. 19, 2013 | Dec. 17, 2022 |
| 8,732,963 | Aug. 22, 2012 | May 20, 2014 | Dec. 17, 2022 |

99. The patents in the '730 family are secondary as they "relat[e] to a drug distribution system for tracking prescriptions of a 'sensitive drug.' " *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC*, 895 F.3d 1347, 1350 (Fed. Cir. 2018).

100. Subsequently the FDA granted pediatric exclusivity extension (to December 16, 2024) for the '730, '106 and '107 patents, and for the '059, '988, '182, and '963 patents (to June 17, 2023). The Patent Trial and Appeal Board ("PTAB") invalidated the '730 family as explained below.

[27] Most '431 family patents were set to expire on December 22, 2019. The '889 and '219 patents, however, received adjustments under 35 U.S.C. § 154(b). In 2018, the FDA granted pediatric exclusivity to the Orange Book-listed patents, and that six-month exclusivity expired June 22, 2020 (for the '506,'650, '275, '619, '062 and '330 patents) and January 4, 2021 (for the '889 and '219 patents).

[28] The '730 family also includes a questionable non-Orange Book United States Patent No. 7,797,171, covering an "exclusive" central computer database for controlled distribution. As this patent was never listed in the Orange Book, it was never included in a Xyrem ANDA application.

**3. The '302 patent family (method of administration).**

101. The parent patent to the '302 family is (filed United States Patent Application No. [ADD] filed on March 15, 2013). The Xyrem-related '302 family of patents listed in the Orange Book are:

**THE '302 PATENT FAMILY: LISTED IN THE ORANGE BOOK**

| U.S. Patent No. | Application Date | Issue Date | Expiry (w/o pediatric exclusivity) |
|---|---|---|---|
| 9,050,302 | Mar. 15, 2013 | June 9, 2015 | Mar. 15, 2033 |
| 8,772,306 | Apr. 29, 2013 | July 8, 2014 | Mar. 15, 2033 |
| 9,486,426 | May 8, 2015 | Nov. 8, 2016 | Mar. 15, 2033 |
| 10,213,400 | Jan. 12, 2018 | Feb. 26, 2019 | Mar. 15, 2033 |

102. The patents in the '302 family asserted methods of treatment for reducing GHB salts in treating sleep disorders when a patient is already taking valproate or divalproex sodium.

103. Subsequently the FDA granted pediatric exclusivity extension to the Orange Book-listed '302 family patents for Xyrem (to September 15, 2033).[29]

**E. Jazz jacks up Xyrem prices "to the Moon."**

104. Prior to exploiting its Xyrem monopoly, Jazz was foundering. Jazz announced a "net loss" of $138.8 million for the 2007 fiscal year.[30]

105. Jazz's initial public offering, held in June 2007, was a disappointment. It missed its target price of $24 to $26 per share, raising $108 million at $18 a share.[31]

106. In 2008 and 2009, Jazz's stock price cratered, and serious questions were raised about its solvency. Jazz had negative equity, meaning its debt exceeded the value of its assets: "[Jazz was] in

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[29] This extension did not apply to the '400 patent, not listed in the Orange Book until 2019, and which is not currently listed in the Orange Book with pediatric exclusivity.

[30] JAZZ PHARMACEUTICALS INC., Fourth Quarter and Full Year 2007 Financial Results, (Feb. 13, 2008), *available at* https://investor.jazzpharma.com/news-releases/news-release-details/jazz-pharmaceuticals-inc-announces-fourth-quarter-and-full-year.

[31] Jazz Pharmaceuticals' IPO falls short, SILICON VALLEY BUSINESS JOURNAL (Jun. 1, 2007), *available at* https://www.bizjournals.com/sanjose/stories/2007/05/28/daily56.html.

default on our debt, literally talking to bankruptcy attorneys every day,"[32] according to its CEO. How did Jazz "turnaround," raising its stock price from $0.53?

107. Jazz increased the price of Xyrem "To the Moon, Alice!"[33]

108. Jazz's price increases started gradually in 2009—it told investors in June 2010 that "[t]otal product sales were $34.3 million in the first quarter, an increase of 61% over the first quarter of 2009 driven primarily by price increases taken on Xyrem during 2009."[34] Its first quarter 2010 revenues roughly equaled its yearly revenue in 2007-2009.

109. On May 1, 2010, Jazz announced a 15% price increase for Xyrem.

110. Jazz assured its investors in a June 2010 investor call that these price increases were sustainable: "it's important to remember that the vast majority of our Xyrem patients have fixed monthly co-pays. These patients should not see any impact to their monthly co-pay from price increase. Approximately 80% of our Xyrem patients have monthly out-of-pocket costs of $50 or less."[35] The reason Jazz had such confidence is because it knew HCSC and other insurers were footing the massive bill.

111. In November 2010, Jazz raised the price of Xyrem another 22%. Robert M. Myers, Jazz's President, explained the strategy with the incremental price increases: "We do want to avoid big jumps in price, abrupt changes in price, which can have a negative impact on payers, physicians and, most importantly, patients."[36] But these steady price increases added up.

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[32] From Foundation, to Darkest Days, to Finest Hour, LIFESCIENCELEADER.COM, (Rob Wright ed.) (June 2015), *available at* https://www.jazzpharma.com/wp-content/uploads/2015/10/Life-Science-Leader.pdf.

[33] Jim Edwards, How a Sleeping Drug Company Increased Prices 300% Without anyone Noticing, CBS NEWS (Nov. 12, 2010), *available at* https://www.cbsnews.com/news/how-a-sleeping-drug-company-increased-prices-300-without-anyone-noticing/.

[34] Jazz Pharmaceuticals, Inc., Q1 2010 Earnings Call Transcript (May 5, 2010), *available at* https://seekingalpha.com/article/203249-jazz-pharmaceuticals-inc-q1-2010-earnings-call-transcript.

[35] *Id.*

[36] Andrew Pollack, Coupons for Patients, but Higher Bills for Insurers, THE NEW YORK TIMES (Jan. 1, 2011), *available at* https://www.nytimes.com/2011/01/02/business/02coupon.html.

112. Jazz CEO [If this is the first mention, give the first name] Cozadd noted Jazz had "substantial pricing power" because there is "nothing else that does what [Xyrem] does. There is no substitute."[37]

113. Jazz's price increases stood out, even in a crowded field of companies that sought to take advantage of patients on maintenance medications needed to treat long-term conditions. "Pharmaceutical industry expert Tracy Staton, from FiercePharma, said the company had increased the cost of Xyrem by more than 800 per cent in seven years. 'Jazz's price increases have been quite large, among the very biggest price increases among drugs in the last 10 years,' she said. 'We did a ranking in 2014 across the industry and Jazz was at the top."[38]

114. Bloomberg published data showing that Jazz increased prices by 841% from 2007 to 2014 alone: "According to Bloomberg data, this year Xyrem costs $19.40 per 1-milliliter dose, up from just $2.04 in 2007--an 841% jump. And it's those price hikes that accounted for most of last year's sales growth, according to the Irish company's annual report. Volume increased by 12% last year, with the price rocking up by nearly one-third."[39]

**F. Jazz seeks multiple pharmacy REMS in conjunction with its request for approval to market Xyrem for fibromyalgia.**

115. As Jazz's ability to raise price was central to its business philosophy, Jazz employed a series of measures to wall off generic competition. Jazz's REMS proposal was one way Jazz managed to restrict competition.

[37] Final Transcript, Jazz Pharmaceuticals Inc. at LCM Annual Healthcare Conference (Nov. 17, 2010), *available at* https://tinyurl.com/y4lchnrs.
[38] S. Scott and M. Griffiths, Drug company behind narcolepsy medicine Xyrem criticized for huge price hikes, ABC NEWS, (Jun. 23, 2017), *available at* https://www.abc.net.au/news/2017-06-24/narcolepsy-xyrem-drug-company-slammed-for-price-hikes/8647626.
[39] Carly Helfand, Xyrem – Jazz Pharmaceuticals, FIERCEPHARMA.COM, (Oct. 14, 2014), *available at* https://www.fiercepharma.com/special-report/xyrem-jazz-pharmaceuticals.

116. After first promulgating a single-pharmacy distribution system, Jazz proposed to change the REMS process in August 2009 by certifying multiple pharmacies for its distribution. In doing so Jazz admitted by implication this would increase access and still be safe.[40]

117. Jazz then sought FDA approval for a new indication of Xyrem in December 2009 to treat fibromyalgia. The FDA rejected this request, by a panel vote of 20-2, which included REMS with "proposed distribution from 15 pharmacies to meet the expected larger demand" for fibromyalgia.[41]

**G. Generic challengers to Xyrem make Paragraph IV certifications.**

118. Roxane, which was subsequently acquired by Hikma, was the first generic drug sponsor for an AB-rated version of Xyrem. Roxane filed its ANDA in July 2010, seeking to market a 500 mg/ml product. Roxane listed multiple Xyrem Orange Book patents (specifically, the '107, '889, '219, '730, '106 patents) in its Paragraph IV certifications. On October 14, 2010 Roxane sent Jazz a Paragraph IV letter that explained these five patents were invalid, unenforceable, and/or not infringed.

**H. Jazz files sham litigation to combat Hikma's threat.**

119. Jazz sued Hikma (formerly Roxanne) on November 22, 2010, alleging infringement of the five patents. In early 2011, Jazz commenced two additional lawsuits to add three more patents.

120. Jazz filed ***nine*** patent infringement lawsuits against Hikma in the United States District Court for the District of New Jersey: 2:10-cv-06108 (covering the '889, '219, '730, '106,'107 patents); 2:11-cv-00660 (the '431, '506 patents); 2:11-cv-02523 (the '059 patent); 2:12-cv-06761 (the '650 patent); 2:12-cv-07459 (the '275 patent); 2:15-cv-01360 (the '203, '306, '619 patents); 2:15-cv-03684 (the '062 patent); 2:16-cv-00469 (the '302 patent); 2:16-cv-04971 (the '963 patent).

121. Jazz's proliferation of litigation was a delay tactic insofar as it gained information from Hikma about its patent defenses in order to fortify its patent portfolio and instigate new infringement lawsuits.

[40] Xyrem Order at 9-12.

[41] Lisa Richwine, "US FDA panel rejects Jazz drug for fibromyalgia," REUTERS (Aug. 20, 2010), *available at* https://www.reuters.com/article/jazz-fda/update-3-us-fda-panel-rejects-jazz-drug-for-fibromyalgia-idUSN2013534120100820.

122. Jazz learned in the first lawsuit (2:10-cv-06108) that Hikma would argue the '219 or '889 patents were non-infringed because Hikma included no "pH adjusting agent." With this knowledge, Jazz filed for and obtained the '650 patent, in which Jazz claimed patent protection for a formulation that also had no "pH adjusting agent" in its formulation. Then it sued Hikma in 2:12-cv-06761 under the '650 patent.

123. Jazz's '506 patent covered "concentrated" medium of sodium oxybate, and Hikma claimed in defense of its infringement suit that Jazz instead used a "diluted medium" in its patent application. In response to this non-infringement defense, Jazz promptly obtained two patents ('650 and '275) in September 2012 that purportedly covered these "diluted medium" applications. Jazz filed two separate patent infringement lawsuits based on these newly-issued patents in October and December 2012.

124. In 2:11-cv-00660, Hikma defended the infringement claim concerning the '431 patent by arguing that the patent required sodium oxybate be added to an "aqueous medium," while Hikma in fact did not add sodium oxybate to an "aqueous medium." In response, Jazz got a patent (the '203) where it claimed no addition of sodium oxybate was required, and sued Hikma under the '203 patent in 2:15-cv-01360.

**I. Jazz reverses course in its REMS negotiations to deter generic entry.**

125. In yet another pivot, Jazz patented its REMS processes, even though it had already admitted that multiple pharmacies were just as safe as a single pharmacy set up.

126. In a November 2011 investor conference, Cozadd said "We have nine patents covering the product, seven of which are in the Orange Book. Those patent dates go out to 2024. Five of the patents are around the restricted distribution system, although there are other patents for formulation and use. The restricted distribution system patents, we think, are particularly important because part of the FDA's approval in sodium oxybate back in 2002 was conditioned on having a very tight distribution system for this controlled substance, in part to ensure that there's not abuse or diversion."[42]

[42] Jazz Pharmaceuticals Inc. Piper Jaffray Health Care Conference Call Transcript, (Nov. 30, 2011), at 6, *available at* https://investor.jazzpharma.com/node/12191/html.

127. The REMS patents were especially important, according to Cozadd: "We think any generic company—Roxane included—will have a difficult time setting up their own distribution system that … doesn't infringe our intellectual property."[43]

128. The FDA has adopted Elements To Assure Safe Use exception ("ETASU") to waive certain burdensome barriers to entry. ETASU "provides safe access for patients to drugs with known serious risks that would otherwise be unavailable," if (i) the burden of forming a single shared system outweighs the benefits of having one; or (ii) an aspect of the REMS is covered by a patent or is a trade secret and the generic applicant certifies that it sought a license for use of that aspect and was unable to obtain one. 21 U.S.C. § 355-1. ETASU introduced the threat that generic companies could get around Jazz's REMS program.

**J. Additional Paragraph IV challengers emerge and face REMS issues.**

129. In October 2012, Roxane sought Jazz's agreement to develop a single shared system REMS.

130. Amneal submitted an ANDA seeking FDA approval to market an AB-rated generic version of Xyrem on December 10, 2012. Jazz sued Amneal after receiving its Paragraph IV notice letter. After Amneal sent its initial Paragraph IV notice letter to Jazz, Jazz filed a patent infringement action against Amneal. This initiated a series of ANDAs and Paragraph IV certifications, as shown below:

| ANDA Applicant | Date of Paragraph IV Letter |
|---|---|
| Amneal Pharmaceuticals, LLC | Dec. 10, 2012 |
| Par Pharmaceutical, Inc. | Nov. 20, 2013 |
| Ranbaxy Laboratories Limited and Ranbaxy Inc. | June 3, 2014 |
| Watson Laboratories, Inc. | Oct. 29, 2014 |
| Wockhardt Bio AG | June 8, 2015 |
| Lupin Ltd. and Lupin Pharmaceuticals, Inc. | July 23, 2015 |

131. Jazz knew that the FDA was likely to reject aspects of its REMS program as unduly restrictive. Jazz noted on September 30, 2013 in an SEC quarterly filing that "depending on the extent to

[43] *Id.* at 7.

which certain provisions of our Xyrem deemed REMS which are currently protected by our method of use patents covering the distribution of Xyrem are changed as part of updating our REMS documents, the ability of our existing patents to protect our Xyrem distribution system from generic competitors may be reduced."[44]

132. As shown above, by December 2013 Jazz faced Paragraph IV challenges from Amneal and Par. Around that time, the FDA informed Jazz that its single pharmacy distribution restriction would need to be modified. Jazz disclosed this in its SEC filings: "[W]e disagree with the FDA's current position that, as part of the current REMS process, the Xyrem deemed REMS should be modified to enable the distribution of Xyrem through more than one pharmacy, or potentially through retail pharmacies and wholesalers, as well as with certain modifications proposed by the FDA that would, in the FDA's view, be sufficient to ensure that the REMS includes only those elements necessary to ensure that the benefits of Xyrem outweigh its risks, and that would, in the FDA's view, reduce the burden on the healthcare system. The FDA notified us that it would exercise its claimed authority to modify our REMS and that it would finalize the REMS as modified by the FDA unless we initiated dispute resolution procedures with respect to the modification of the Xyrem deemed REMS. Given these circumstances, we initiated dispute resolution procedures with the FDA at the end of February 2014. We received the FDA's denial of our initial dispute resolution submission in the second quarter of 2014 and have submitted a request for further supervisory review to the next administrative level of the FDA."[45]

133. While it was resisting the FDA's efforts to modify the Xyrem REMS to allow for multiple pharmacies, Jazz was obstructing ANDA applicants who were seeking to meet their obligation to participate in a singled shared system REMS.

134. Generic ANDA filers began to raise their concerns to the FDA, which was at the same time dealing with Jazz's frivolous appeals of its actions concerning single-pharmacy REMS set up.

135. In February 2015, the FDA approved Jazz's single-pharmacy plan but noted both Jazz's inconsistent positions and the anticompetitive nature of Jazz's conduct: "the FDA has sought to finalize

[44] Jazz Pharmaceuticals Inc. SEC Form 10-Q at 54 (filed Nov. 5, 2013).
[45] Jazz Pharmaceuticals Inc. SEC Form 10-Q at 8, (filed Aug. 5, 2014).

and approve the REMS for Xyrem since 2008. In doing so, we have faced repeated, lengthy delays. The REMS you submitted on November 7, 2014, which we are now approving, contains a requirement that Xyrem be distributed only by a single pharmacy. Jazz's position that a single pharmacy is critical to the safe use of Xyrem has not been a consistent one. In 2009, Jazz submitted a supplemental NDA for a new indication for Xyrem for treatment of fibromyalgia in which it proposed to include multiple certified pharmacies. However, by early 2011, after FDA declined to approve the fibromyalgia indication, Jazz changed its position. By that time, Jazz had been granted several patents related to its single pharmacy distribution system. In its 2013 SEC filings, Jazz noted that it expected FDA modifications to the Xyrem REMS and stated that, 'depending on the extent to which certain provisions of our Xyrem deemed REMS which are currently protected by our method of use patents covering the distribution of Xyrem are changed as part of updating our REMS documents, the ability of our existing patents to protect our Xyrem distribution system from generic competitors may be reduced.' This statement, in conjunction with Jazz's change in position regarding the necessity of the single pharmacy requirement, suggests Jazz's awareness that the Xyrem REMS could have the effect of blocking or delaying approval of generic versions of Xyrem. Such an outcome would reflect the use of REMS to block or delay generic competition in a manner inconsistent with section 505-1(f)(8). It would also place an unjustified burden on patient access and on the healthcare delivery system."[46]

136. Jazz promptly sought to take advantage of generic entrants by refusing to cooperate with them and interfere with their ability to get FDA approval. Jazz's conduct caused the FDA to waive the single-pharmacy requirement, a reversal of the FDA's prior decision to reluctantly approve it: "On January 17, 2017, in response to generic manufacturer's allegations, the FDA waived the single-pharmacy requirement for generic versions of Xyrem. In issuing this waiver, the FDA reiterated generic manufacturer's allegations that 'Jazz ha[d] engaged in a strategy that 'entails serial attempts to impose

[46] Letter from William H. Dunn to Jennifer Ekelund, dated Feb. 27, 2015 at 3, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/021196Orig1s015ltr.pdf.

unreasonable contractual terms and conditions on the ANDA [filers] while concurrently issuing self-serving statements to FDA and the ANDA [filers] about Jazz's commitment to the process.' "[47]

137. "The FDA then found that the 'burden of creating a single, shared system outweighs the benefits.' . . . . Among the burdens were Jazz's 'obvious incentives' 'to delay generic competition [] by failing to agree on [single, shared system] REMS terms.' . . . . The FDA thus concluded that allowing ANDA applicants to proceed with their own drug distribution systems would 'remove a barrier to generic products coming to market.' "[48]

**K. The '730 patents are declared invalid in *inter partes* review.**

138. Beginning in January 2015, Par and Amneal sought *inter partes* review ("IPR") before the PTAB of Jazz's '730 family of patents (specifically, the '730, '106, '107, '059, '988, '182, and '936 patents). Wockhardt and Ranbaxy also sought IPR of this family of patents.

139. On April 28, 2016, Jazz settled with Wockhardt and granted Wockhardt a license to manufacture, market, and sell its generic version of Xyrem on or after December 31, 2025, or "earlier depending on the occurrence of certain events" (the import of which is discussed below).

140. Jazz settled with Ranbaxy next, on May 9, 2016, granting it a license to manufacture, market, and sell its generic version of Xyrem on or after December 31, 2025, or "earlier depending on the occurrence of certain events."

141. These settlements resolved Wockhardt and Ranbaxy's IPRs.

142. Amneal and Par's IPRs were resolved in decisions by the PTAB from July 2016 to March 2017, finding that "by a preponderance of the evidence" all claims of the '730, '106, '107, '059, '182, '988 patents, and claims 24, 26, and 27 of the '963 patent, were unpatentable as obvious.

143. The PTAB found that these claims, which related to Jazz's REMS program and described a centralized database containing patient, physician, and prescription information, were obvious because Orphan Medical had disclosed the program at a publicly-held FDA Advisory Committee meeting on June 6, 2001)—long before it filed the first patent application.

[47] Xyrem Order at 11.
[48] *Id.*

144. Jazz appealed the ruling to the Federal Circuit. In July 2018, the Federal Circuit affirmed the PTAB invalidity rulings.

**L. The Jazz-Hikma reverse payment agreement.**

145. Hikma obtained final approval from the FDA for its AB-rated generic Xyrem product on January 17, 2017.

146. Hikma's patent infringement trial with Jazz was set for July 2017. Hikma's prospects of bringing a generic product to market were bolstered by the FDA's decision to waive the single-pharmacy REMs requirement, as noted above.

147. Jazz publicly announced a settlement with Hikma on April 5, 2017, in an SEC Form 8-K: "In connection with the settlement, Jazz has granted Hikma and its wholly owned subsidiary, West-Ward Pharmaceuticals Corp. (West-Ward), the right to sell an authorized generic (AG) version of Xyrem in the U.S. under the Xyrem New Drug Application (NDA), commencing on January 1, 2023, or earlier under certain circumstances customary for settlement agreements of this nature. The AG product will be marketed through the Xyrem Risk Evaluation and Mitigation Strategy (REMS) program. The initial term of the AG arrangement is six months, and Hikma has the option to continue the sale of the AG product for up to a total of five years. Jazz will receive a meaningful royalty on net sales of the AG product, with the royalty rate increasing during the initial AG term based on increased AG sales. There will be a substantial increase in the royalty rate should the AG term be extended beyond one year. Jazz will also be paid for supply of the AG product and will be reimbursed for a portion of the service costs associated with the operation of the Xyrem REMS and distribution of the AG. Specific financial and other terms related to the AG product are confidential. Hikma has been granted a license to sell its generic sodium oxybate product under its ANDA at the end of the AG term."

148. The settlement resolved litigation pending since 2010. Although some details of the settlement were public, many were kept secret. Jazz concealed the terms of the "no AG" agreement as well as the details of the licensing agreement.

149. A "no AG" agreement was necessary because Hikma knew that even if it were successful at trial Jazz would have launched an authorized generic, undercutting the value of the victory.

150. Taken together the Jazz-Hikma settlement had three reverse payments.

151. "First, Jazz promised not to license AG to any third party other than Hikma between at least January 1, 2023 and July 1, 2023. Second, Jazz created a royalty structure of escalating payments from Hikma to Jazz that undermined Jazz's economic interest in marketing its own AG. … Third, the Jazz-Hikma agreement contained an 'acceleration clause.' … An acceleration clause is a type of most-favored-entry clause that allows a generic manufacturer to enter a market sooner if certain contingencies occur . . . . In the Jazz-Hikma agreement, the acceleration clause allegedly allowed Hikma to immediately market Hikma Authorized Generic ('AG') if (1) a generic version of Xyrem were to market itself without Jazz's permission; or (2) anyone were to successfully invalidate or render unenforceable Xyrem's unexpired patent claims."[49]

152. Acceleration agreements like this deter generic entry because it ensures generic entrants face competition if they enter the market, thereby making entry less valuable.[50]

153. As noted above, and explained in further detail below, Jazz weaponized the acceleration clause in the Jazz-Hikma agreement against later generic challengers Par, Lupin, and Amneal.

154. Under the Jazz-Hikma Agreement, Jazz granted Hikma the right to sell an authorized generic version of Xyrem in the U.S. for an initial term of six months commencing on January 1, 2023 "or earlier under certain circumstances." Those circumstances include "the licensing or market entry of another generic sodium oxybate product, a final decision that all unexpired claims of the Xyrem patents are invalid and/or unenforceable, or a substantial reduction in Xyrem net sales over specified periods of time. We also granted [Hikma] a license to launch its own generic sodium oxybate product as early as six months after it has the right to sell the AG Product, unless it elects to continue to sell the AG Product, which it may do for up to a total of five years."[51]

155. In return, Hikma agreed to pay Jazz "a meaningful royalty" on net sales of the AG, with the royalty rate increasing based on increased net sales of the authorized generic. The Jazz-Hikma the

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[49] Xyrem Order at 14.

[50] *See* Keith M. Drake & Thomas G. McGuire, *Generic Entry Before the Agreed-Upon Date in Pharmaceutical Patent Settlements*, 16 J. COMPETITION L. & ECON. 188, 188 (2020).

[51] Jazz Pharmaceuticals Inc., 2017 SEC Form 10-K at 5 (filed Feb. 27, 2018).

agreement had a royalty provision that operated to delay price competition. It "created a royalty structure that will charge Hikma a royalty rate that increases with Hikma's market share. This escalating royalty structure (1) disincentivizes output because 'market share' is defined in terms of unit volume (e.g., number of bottles); and (2) incentivizes higher prices because Jazz and Hikma can boost revenue while keeping volume low by raising prices."[52]

156. Although Hikma has a license to launch a generic product as of July 1, 2023, if it does so, Hikma will no longer have the right to sell an AG product through the Xyrem REMS.

157. Hikma agreed to purchase its supply from Jazz and distribute the AG through the Jazz REMS. According to Jazz's 2017 10-K, Jazz "will also receive payment for the supply of the [Hikma] AG Product and reimbursement for a portion of the services costs associated with the operation of the Xyrem REMS and distribution of the [Hikma AG Product]."

158. Jazz also granted Hikma a non-exclusive license under the Xyrem patents to make, have made, and market its generic sodium oxybate product under the Roxane ANDA in the U.S., which license was to be effective after the end of the AG sales period. Hikma agreed that it would not otherwise make, use, or sell a generic version of Xyrem for "so long as the Xyrem Patents remain in effect."

159. Finally, under the guise of "attorneys' fees," Jazz made a cash payment to Hikma that was redacted from the 8-K: "Jazz shall make a one-time payment of [REDACTED] by wire transfer to an account designated by Roxane, in recognition of the savings inuring to Jazz in terms of the avoidance of costs and expenditure of time and resources associated with prosecuting the Actions."[53] This cash payment was another reverse payment.

### M. Jazz enters into unlawful reverse payment agreements with Par, Lupin, and Amneal: The Later Generic Defendants.

160. In 2017 Ascent Pharmaceuticals, Inc. and Mallinckrodt submitted ANDA applications, in June and November. Jazz filed patent infringement actions against them in the U.S. District Court for the District of New Jersey.

[52] Xyrem Order at 49.

[53] Jazz Pharmaceuticals Inc., 2017 SEC Form 10-K at 79 (filed Feb. 27, 2018).

161. Ascent abandoned its challenge, and Jazz gave notice of dismissal of its action, 2:17-cv-05487, on August 29, 2017.

162. Mallinckrodt abandoned its challenge, and Jazz gave notice of dismissal of its action, 2:18-cv-00029, on June 15, 2018.

163. But generic challenges from Par, Lupin, and Amneal would continue.

164. Jazz entered into reverse payment agreements with Par, Lupin, and Amneal that also had three reverse payments.

165. "First, Jazz made multi-million-dollar cash payments to each Later Generic Defendant—ostensibly for Jazz's avoided litigation costs.… Second, Jazz allegedly gave each Later Generic Defendant a limited license to sell a constrained supply of AG. Each license (1) began only after the expiration of Hikma's 180-day exclusivity period in July 2023; (2) was capped at a low-single-digit market share; and (3) required a royalty payment, as a percentage of sales, that increased over time. … Third, Jazz's agreements with each Later Generic Defendant contained acceleration clauses like the acceleration clause in the Jazz-Hikma agreement discussed above.…"[54]

166. In January 2018, Jazz granted Par a right to sell a limited volume of an authorized generic version of Xyrem (the "Par AG") for a term beginning July 1, 2023, or earlier under certain circumstances, and ending on December 31, 2025. This "Jazz-Par Agreement" further allocated the market for the Xyrem AG by giving Par the ability to sell "a low single digit percentage" of Xyrem sales volume during the calendar year preceding the entry date of the Par AG. In effect, Jazz simply agreed to pay to Par a share of the supracompetitive profits it was gaining through the anticompetitive conditions it had created.

167. In June 2018, Jazz granted Lupin a right to sell a limited volume of an authorized generic version of Xyrem (the "Lupin AG") for a term beginning July 1, 2023, or earlier under certain circumstances, and ending on December 31, 2025. This "Jazz-Lupin Agreement" further allocated the market for the Xyrem AG by giving Lupin the ability to sell "a low single digit percentage" of Xyrem sales volume.

[54] Xyrem Order at 15-16.

168. In October 2018, Jazz granted Amneal a right to sell a limited volume of an authorized generic version of Xyrem (the "Amneal AG") for a term beginning July 1, 2023, or earlier under certain circumstances, and ending on December 31, 2025. This "Jazz-Amneal Agreement" further allocated the market for Xyrem AG by giving Amneal the ability to sell "a low single digit percentage" of Xyrem sales volume.

169. In exchange for their respective share of Jazz's brand Xyrem revenue (via volume-limited AG supply), Par, Lupin, and Amneal each agreed to abandon their challenge to Jazz's patents and delay launch of their own AB-rated generic until December 31, 2025.

170. Each of the Par, Lupin, and Amneal Agreements had cash payments that were suspicious under *Actavis* because they were "multi-million-dollar cash payments" "ostensibly for Jazz's avoided litigation costs." [55]

171. With respect to the Par, Lupin, and Amenal Agreements, the use of fractionalized allocation was done to incentivize high prices for Xyrem. In the Agreements, "market share [is] defined by total units sold—again incentivizing higher prices because volumes were capped."[56]

172. Each of the Par, Lupin, and Amneal Agreements also included an "acceleration clause" that allows earlier entry if the Jazz patents were invalidated, another generic manufacturer entered the market, or there is a substantial reduction in Xyrem net sales over a specified period of time.

173. Par, Lupin, and Amneal all made conscious decisions to restrict or block generic entry, throttle competition for Xyrem, and became part of the scheme to allocate the market for Xyrem.

174. At the time of entering into the Jazz-Amneal Agreement, Amneal was aware of the arrangements between Jazz, Hikma, Lupin, and Amneal.

175. As with the Jazz-Hikma Agreement, Jazz's agreements with Par, Lupin, and Amneal will not increase overall output, reduce price, or increase consumer choice; they will merely substitute Par, Lupin, and Amneal as the sellers of millions of dollars' worth of Xyrem for the sole purpose of paying them to delay market entry of less-expensive generic sodium oxybate, preserving Jazz's massive monopoly profits in exchange for doling out a small slice of them to Par, Lupin, and Amneal.

[55] *Id.* at 42.
[56] *Id.* at 50.

**N. The Jazz-Hikma agreement has caused, and will continue to cause, anticompetitive effects.**

176. The Jazz-Hikma Agreement has numerous anticompetitive effects, most prominently that Hikma abandoned its patent challenge and could have entered the market after trial in July 2017 or shortly thereafter. Other generic entrants such as Par, Lupin, and Amneal could have entered 180 days thereafter.

177. Jazz and Hikma could have, and would have absent their illegal agreement, settled for terms that did not include several illegal reverse payments.

178. The same is true for Par, Lupin, and Amneal.

179. Had these reverse payments not been reached, there would be agreed upon generic entry prior to July 2023.

180. The Jazz-Hikma agreement has an "implicit" "no AG" agreement. "As circumstantial evidence of an implicit no-AG agreement, [Plaintiff] rel[ies] on explicit parts of the Jazz-Hikma agreement. These parts of the Jazz-Hikma agreement allegedly (1) disincentivized Jazz from marketing its own AG; and (2) further compensated Hikma in order 'to maintain supracompetitive prices to be shared among the patentee [here, Jazz] and the challenger [here, Hikma] rather than face what might have been a competitive market.' "[57]

181. The Jazz-Hikma agreement has several poison pills that disincentivized Hikma from entering the market with its own generic before July 2023. If Hikma entered, it would have forfeited the ability to use Jazz's REMS, causing Jazz to launch an AG, and after 180 days, other generic entrants would have entered and reduced Hikma's profits. Thus, the Jazz-Hikma agreement locked up Hikma's ability to market its own product.

182. Jazz also used the "acceleration clause" in the Jazz-Hikma Agreement to cause a roadblock to Par, Lupin, and Amneal. The "acceleration clause" destroyed the value of any successful challenge because victory would only mean that Hikma and Jazz, through an AG, would immediately compete. In this way, the Par, Lupin, and Amneal Agreements allocated the market by ensuring the

[57] *Id.* at 30-31 (quoting *F.T.C. v. Actavis*, 570 U.S. 136, 157 (2013)).

challengers would take the payoff of high prices for their fractional share of Jazz's AG rather than seek to introduce true generic competition.

183. The royalty provisions in the Jazz-Hikma Agreement undermined price competition because Hikma got a higher royalty rate if it increased its market share: "This escalating royalty structure (1) disincentivizes output because 'market share' is defined in terms of unit volume (e.g., number of bottles); and (2) incentivizes higher prices because Jazz and Hikma can boost revenue while keeping volume low by raising prices."[58]

184. The value of Jazz's reverse payment to Hikma alone is at least $480 million and as much as $705 million.[59] The logic of these estimate is that without having to contend with Hikma, Jazz could continue its price increases, and grow its sales steadily (as it had done before) from $1.5 billion in sales in 2018 until at least 2023. Had Hikma entered with a generic product, however, Jazz's profits would have been greatly reduced over the same period, as generic entry would have reduced the price of Xyrem immediately by as much as 50%, with 80% or more of the market going to the AB-rated generic.

185. The fractional share of value to Par, Lupin, and Amneal is worth tens of millions of dollars. Assuming $2 billion in annual sales, a modest projection from Jazz's 2020 brand revenues of $1.74 billion,[60] and that an authorized generic would be discounted by 10%, each 1% allocated to Par, Lupin, and Amneal would be worth $20 million.[61]

186. Jazz touted the anticompetitive effects of the agreements. "At a conference on December 4, 2019, Jazz's CEO stated that 'in terms of dynamics on price, it's – th[e] [market] is not what you would think of as a generic free for all' because of the 'very limited volumes' for Par, Lupin, and Amneal. … Similarly, on November 14, 2018, a senior Jazz executive explained that 'after th[e] [] 6-

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[58] *Id.* at 49.
[59] *Id* at 57-58.
[60] Jazz Pharmaceuticals plc, Jazz Pharmaceuticals Announces Full Year and Fourth Quarter 2020 Financial Results, (Feb. 23, 2021), *available at* https://investor.jazzpharma.com/news-releases/news-release-details/jazz-pharmaceuticals-announces-full-year-and-fourth-quarter-2020#:~:text=Xyrem%20net%20product%20sales%20increased,the%20same%20periods%20in%202019.
[61] Calculated as $2 billion x 90% x 1%.

month exclusivity period for the first-filer [Hikma], 3 of the second filers [allegedly Par, Lupin, and Amneal] get to come again with a limited generic. And they are limited to low single-digit volume of the previous year Xyrem sales. So again, relatively low incursion on Xyrem here."[62]

187. In November 2020 Jazz launched Xywav, a therapeutic equivalent of Xyrem. Jazz priced Xywav just below the priceq1 of Xyrem, in a further attempt to provide an obstacle for generic entry of Xyrem. Jazz hopes to convert the market for Xyrem to Xywav, such that when generic versions of Xyrem do eventually enter the market, the market will have shifted to Xywav.

## VI. DEFENDANTS' ANTICOMPETIVE EFFECTS IN THE MARKET FOR SODIUM OXYBATE

188. Jazz's conduct as described above harmed competition in at least several respects.

189. *First*, Jazz's REMS process (and its manipulation of the FDA approved protocol in this respect) initially required a single certified distributor and interfered with downstream competition on price among competing distributors.

190. *Second*, Jazz interfered with and refused to cooperate with generic drug companies that sought FDA approval, creating a barrier to entry.

191. *Third*, Jazz confounded generic entry by taking inconsistent positions with its REMS programs, manipulating the statutory and regulatory mechanisms by which generic competition takes place.

192. *Fourth*, Jazz engaged in sham litigation, taking shifting positions in mushrooming litigation in the District of New Jersey.

193. *Fifth*, Jazz entered into pay-for-delay agreements, blocked and delayed generic entry, and allocated the market for Xyrem and its AB-rated equivalents among Defendants.

194. Jazz interfered with the normal operation of market conditions by throttling generic entry through market allocation that was intended to, and would have the effect of, preventing full price competition to Xyrem from AB-rated generic equivalents. This deprives consumers and Plaintiff of the

[62] Xyrem Order at 11.

benefit of generic competition in the form of discounted AB-rated generic Xyrem. Jazz's scheme prevented generic competition—which could have occurred as early as July 2017.

195. There is no procompetitive justification or consumer benefit to Jazz's self-serving scheme. Generic drugs offer enormous cost savings, which outweigh any non-pretextual, if there even are any, justifications Jazz could possibly offer.

## VII. JAZZ'S MONOPOLY POWER

196. Jazz has 100% of the share in the market for sodium oxybate.

197. It has exercised its market power to exclude competition, and to raise the price of Xyrem substantially without losing enough sales to make the price increases unprofitable.

198. Jazz has serially and continually increased prices of Xyrem, as alleged above, generating substantial profits.

199. Only AB-rated generic Xyrem could take significant sales away from Xyrem. A small but significant price increase in Xyrem would not cause Jazz to lose significant sales of Xyrem.

200. Branded Xyrem has no significant cross-price elasticity with any other pharmaceutical product, including any treatment for narcolepsy.

201. There is no therapeutic substitute for Xyrem because other pharmaceutical products that treat cataplexy and/or EDS are not therapeutically equivalent. Physicians typically prescribed Xyrem in addition to other treatments for narcolepsy, such as amphetamines or wakefulness drugs. The fact that Xyrem is not a therapeutic substitute for those other products is demonstrated by the fact that lower-priced generic versions of those products were available during the conduct period, but those lower-priced generic drugs did not take market share from Xyrem.

202. Direct evidence of Jazz's market power includes the fact that AB-rated Xyrem would have entered the market at a steep discount to Xyrem, and only AB-rated Xyrem could take significant sales away from Xyrem.

203. Direct evidence of market power also includes Jazz's gross margins on Xyrem (in excess of 90%), and also that Jazz repeatedly and profitably raised prices of Xyrem.

204. Further direct evidence is shown by the fact that Jazz never lowered the price of Xyrem in response to competition from any other treatment or product.

205. In the alternative, and to the extent Plaintiff must indirectly define a market, the relevant product market is sodium oxybate—Xyrem, Xywav, and its AB-rated generic equivalents. The relevant geographic market is the United States.

## VIII. EFFECTS ON TRADE AND COMMERCE

206. The drugs at issue in this case are sold in interstate commerce. Defendants' unlawful activities, as alleged above, have occurred in, and have had a substantial impact on, interstate commerce.

207. At all material times, Xyrem, manufactured and sold by Jazz, was shipped across state lines and sold to customers outside its state of manufacture. Jazz directed the sale of Xyrem throughout the United States and into California.

208. Defendants' unlawful activities, as described in this Complaint, affected both intrastate commerce in the states in which HCSC's health plans purchased Xyrem for their members, and interstate commerce flowing into or out from California.

209. At all relevant times, HCSC was contractually responsible for the payments for the drugs at issue dispensed to HCSC's Insureds.

210. The anticompetitive acts by Defendants and their co-conspirators had, and continue to have, a direct, substantial, and reasonably foreseeable effect on California trade and commerce, including by artificially raising and fixing prices for the drugs at issue, as were paid in, and/or out from, California, and otherwise injuring corporations and persons located in California.

## IX. ANTITRUST INJURY

211. There is currently no AB-rated generic Xyrem on the market. Absent Defendants' conduct, there would have been one as early as January 2018.

212. HCSC has paid and will continue to pay. substantially inflated prices for Xyrem due to Defendants' scheme to frustrate and delay generic entry of AB-rated generic Xyrem.

213. The price of Xyrem was artificially inflated, and price competition from AB-rated generic Xyrem was curtailed.

214. Defendants' scheme is the proximate cause of HCSC's injuries. But for Defendants' efforts to keep AB-rated generic Xyrem off the market, there would be substantially lower prices for Xyrem.

215. HCSC would have substantial savings if the scripts for brand Xyrem were instead, as they would have been, scripts for AB-rated generic Xyrem. The absence of generic substitution and competition caused HCSC to pay overcharges for Xyrem that continue to the present.

216. HCSC will present evidence of the quantum of overcharges it has paid at trial in the form of econometric analysis.

217. HCSC suffered injury when it paid for prescriptions of Xyrem, at inflated prices, for members located across the United States. Defendants' conduct had a substantial effect on HCSC's business operations in these states because HCSC's health plans purchased Xyrem for members located in these states.

218. Antitrust injury is further shown by, as explained above, the fact that the "alleged reverse payments are plausibly large and unexplained," and "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself."[63]

## X. HCSC'S CLAIMS ARE TIMELY

### A. Defendants fraudulently concealed important terms of their unlawful agreements.

219. Defendants fraudulently concealed significant anticompetitive terms in the unlawful agreements they struck with Hikma and the other Later Filed Generics.

220. The full terms of the April 2017 Jazz-Hikma agreement were concealed from the public, as explained above. Jazz and Hikma suppressed their tacit agreements, as well as the implied "no AG" agreement.

221. The "implicit" 'no-AG' agreement is that Jazz will not sell an authorized generic of Xyrem for 'at least the first six months that Hikma is eventually on the market' with the Hikma AG,

[63] Xyrem Order at 57.

which is Jazz's Xyrem under the label of Hikma AG."[64] Although the agreements appeared to give Jazz the ability to launch its own AG, these provisions were illusory: "Plaintiffs plausibly allege the existence of an implicit or de facto no-AG agreement between Jazz and Hikma. As circumstantial evidence of an implicit no-AG agreement, Plaintiffs rely on explicit parts of the Jazz-Hikma agreement. These parts of the Jazz-Hikma agreement allegedly (1) disincentivize Jazz from marketing its own AG; and (2) further compensate Hikma …. Plaintiffs specifically identify three parts of the Jazz-Hikma agreement that disincentivize a Jazz AG and convey value to Hikma. The first is Jazz's promise not to license Jazz's AG through any third party for six months. The second is the royalty structure, which escalates kickbacks from Hikma to Jazz to undermine Jazz's economic interest in competing to sell Jazz's own AG. The third is the Jazz-Hikma agreement's 'acceleration clause,' a type of most-favored-entry clause that allows Hikma to sell AG immediately if (1) a generic version of Xyrem were to market itself without Jazz's permission; or (2) anyone were to successfully invalidate or render unenforceable Xyrem's unexpired patent claims."[65]

222. The true state of affairs concerning the Jazz-Hikma agreement was concealed from HCSC until the secret documents were disclosed in the briefing in the *Xyrem Antitrust* litigation motion to dismiss.

223. Accordingly, HCSC may recover damages reaching back beyond four years before the filing of this Complaint.

224. HCSC had no knowledge of the terms of Defendants' agreements and did know the nature and extent of the scheme alleged. Nor could it have discovered the scheme and conspiracy through the exercise of reasonable diligence more than four years before the filing of this Complaint.

225. Defendants actively concealed the existence of the significant terms of their unlawful agreements and their ongoing scheme.

**B. Defendants' continuing violations.**

226. HCSC alleges a scheme that is a continuing course of wrongdoing that includes actions taken within the limitations period.

[64] Xyrem Order at 25.
[65] *Id.* at 30-31.

227. Each time HCSC's health plans purchased brand or AB-rated generic Xyrem at an inflated price, a claim accrued. Each such sale was an overt action taken by Defendants in furtherance of the scheme alleged herein. A cause of action accrued to HCSC each time it paid an overcharge—i.e., each time it made a payment for Xyrem at a price higher than would have been paid absent Defendants' unlawful conduct. HCSC began to pay overcharges as early as July 17, 2017.

228. HCSC reserves the right to allege that it began to pay overcharges at an earlier time based on evidence disclosed in discovery. Jazz's agreements with Hikma have not been made public, nor have the agreements with Par, Lupin, and Amneal.

## XI. CLAIMS FOR RELIEF

### COUNT I

### CONSPIRACY AND COMBINATION IN RESTRAINT OF TRADE UNDER STATE LAW

(AGAINST JAZZ AND HIKMA)

229. HCSC incorporates by reference the preceding allegations.

230. Jazz and Hikma entered into an agreement or combination in restraint of trade in violation of many states' laws. Jazz and Hikma engaged in a continuing contract, combination or conspiracy with respect to the sale of Xyrem in unreasonable restraint of trade and commerce, in violation of the various state antitrust statutes set forth below.

231. Jazz and Hikma entered into an unlawful reverse payment agreement that restrained, and continues to restrain, competition in the market for Xyrem and/or its AB-rated generic equivalents.

232. Jazz and Hikma's acts and combinations in furtherance of the conspiracy have caused unreasonable restraints in the market for Xyrem and/or its AB-rated generic equivalents.

233. As a result of Jazz and Hikma's unlawful conduct, Plaintiff has been harmed by being forced to pay artificially inflated, supracompetitive prices for Xyrem.

234. In formulating and carrying out the alleged agreement, understanding, contract, combination, and conspiracy, Jazz and Hikma did those things that they combined and conspired to do, including but not limited to the acts, practices and course of conduct set forth herein.

235. Jazz and Hikma's conspiracy had the following effects, among others: the reverse payment agreement between Jazz and Hikma delayed generic entry and its attendant lower prices for Plaintiff, and the market allocation output restriction agreement effectively fixed prices at an artificially high level.

236. Jazz and Hikma engaged in the actions described above for the purpose of carrying out their unlawful agreements to fix, raise, maintain, or stabilize prices of Xyrem.

237. There was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on HCSC and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve the purpose. Accordingly, these acts constitute violations of the antitrust laws of various states in accordance with *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

238. By engaging the foregoing conduct, Jazz and Hikma intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of the following state antitrust laws:

a) Arizona Rev. Stat. §§ 44-1401, et seq., with respect to purchases in Arizona.

b) Cal. Bus. & Prof. Code §§ 16700, et seq., with respect to purchases in California.

c) C.G.S.A. §§ 35-26 and 28, et seq., with respect to purchases in Connecticut.

d) D.C. Code §§ 28-4501, et seq., with respect to purchases in the District of Columbia.

e) Haw. Rev. Stat. §§ 480-1, et seq., with respect to purchases in Hawaii.

f) 740 Ill. Comp. Stat. 10/1, et seq., with respect to purchases in Illinois.

g) Iowa Code § 553.1, et seq., with respect to purchases in Iowa.

h) Kan. Stat. Ann. § 50-101, et seq., with respect to purchases in Kansas.

i) Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to purchases in Maine.

j) MD Code Ann., Com. Law, §§ 11-204, et seq., with respect to purchases in Maryland.

k) Mass. Gen. Laws ch. 93A, §§ 1 et seq., with respect to purchases in Massachusetts.

l) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases in Michigan.

m) Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. §§ 8.31, et seq., with respect to purchases in Minnesota.

n) Miss. Code Ann. §§ 75-21-1, et seq., with respect to purchases in Mississippi.

o) Neb. Rev. Stat. Ann. §§ 59-801, et seq., with respect to purchases in Nebraska.

p) Nev. Rev. Stat. Ann. §§ 598A.010, et seq., with respect to purchases in Nevada.

q) N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to purchases in New Hampshire.

r) N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases in New Mexico.

s) N.Y. Gen. Bus. Law § 340, et seq., with respect to purchases in New York.

t) N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases in North Carolina.

u) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases in North Dakota.

v) Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases in Oregon.

w) P.R. Laws Ann. tit. 10 §§ 258, et seq., with respect to purchases in Puerto Rico.

x) R.I. Gen. Laws §§ 6-36-1 et seq., with respect to purchases in Rhode.

y) S.D. Codified Laws §§ 37-1-3.1, et seq., with respect to purchases in South Dakota.

z) Tenn. Code Ann §§ 47-25-101, et seq., with respect to purchases in Tennessee.

aa) Utah Code Ann. §§ 76-10-3101, et seq., with respect to purchases in Utah.

bb) W.Va. Code §§ 47-18-1, et seq., with respect to purchases in West Virginia.

cc) Wis. Stat. §§ 133.01, et seq., with respect to purchases in Wisconsin.

239. HCSC has been injured in their business or property by reason of Jazz and Hikma's violations of the laws set forth above, in that they were, and continue to be: (i) denied the opportunity to purchase lower-priced generic Xyrem; and (ii) paid higher prices for Xyrem than they would have paid but for Jazz and Hikma's unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes Jazz and Hikma's conduct unlawful.

240. HCSC seeks damages and multiple damages as permitted by law.

**COUNT II**

**CONSPIRACY AND COMBINATION IN RESTRAINT OF TRADE UNDER STATE LAW**

(AGAINST JAZZ AND AMNEAL)

241. HCSC incorporates by reference the preceding allegations.

242. Jazz and Amneal entered into an agreement or combination in restraint of trade in violation of many states' laws. Jazz and Amneal engaged in a continuing contract, combination, or conspiracy with respect to the sale of Xyrem in unreasonable restraint of trade and commerce, in violation of the various state antitrust statutes set forth below.

243. Jazz and Amneal entered into an unlawful reverse payment agreement that restrained, and continues to restrain, competition in the market for Xyrem and/or its AB-rated generic equivalents.

244. Jazz and Amneal's acts and combinations in furtherance of the conspiracy have caused unreasonable restraints in the market for Xyrem and/or its AB-rated generic equivalents.

245. As a result of Jazz and Amneal's unlawful conduct Plaintiff has been harmed by being forced to pay artificially inflated, supracompetitive prices for Xyrem.

246. In formulating and carrying out the alleged agreement, understanding, contract, combination, and conspiracy, Jazz and Amneal did those things that they combined and conspired to do, including but not limited to the acts, practices and course of conduct set forth herein.

247. Jazz and Amneal's conspiracy had the following effects, among others: the reverse payment agreement between Jazz and Amneal delayed generic entry and its attendant lower prices for Plaintiff, and the market allocation output restriction agreement effectively fixed prices at an artificially high level.

248. Jazz and Amneal engaged in the actions described above for the purpose of carrying out their unlawful agreements to fix, raise, maintain, or stabilize prices of Xyrem.

249. There was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on HCSC and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve the purpose. Accordingly, these acts constitute violations of the antitrust laws of various states in accordance with *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

250. By engaging the foregoing conduct, Jazz and Amneal intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of the following state antitrust laws:

a) Arizona Rev. Stat. §§ 44-1401, et seq., with respect to purchases in Arizona.

b) Cal. Bus. & Prof. Code §§ 16700, et seq., with respect to purchases in California.

c) C.G.S.A. §§ 35-26 and 28, et seq., with respect to purchases in Connecticut.

d) D.C. Code §§ 28-4501, et seq., with respect to purchases in the District of Columbia.

e) Haw. Rev. Stat. §§ 480-1, et seq., with respect to purchases in Hawaii.

f) 740 Ill. Comp. Stat. 10/1, et seq., with respect to purchases in Illinois.

g) Iowa Code § 553.1, et seq., with respect to purchases in Iowa.

h) Kan. Stat. Ann. § 50-101, et seq., with respect to purchases in Kansas.

i) Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to purchases in Maine.

j) MD Code Ann., Com. Law, §§ 11-204, et seq., with respect to purchases in Maryland.

k) Mass. Gen. Laws ch. 93A, §§ 1 et seq., with respect to purchases in Massachusetts.

l) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases in Michigan.

m) Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. §§ 8.31, et seq., with respect to purchases in Minnesota.

n) Miss. Code Ann. §§ 75-21-1, et seq., with respect to purchases in Mississippi.

o) Neb. Rev. Stat. Ann. §§ 59-801, et seq., with respect to purchases in Nebraska.

p) Nev. Rev. Stat. Ann. §§ 598A.010, et seq., with respect to purchases in Nevada.

q) N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to purchases in New Hampshire.

r) N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases in New Mexico.

s) N.Y. Gen. Bus. Law § 340, et seq., with respect to purchases in New York.

t) N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases in North Carolina.

u) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases in North Dakota.

v) Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases in Oregon.

w) P.R. Laws Ann. tit. 10 §§ 258, et seq., with respect to purchases in Puerto Rico.

x) R.I. Gen. Laws §§ 6-36-1 et seq., with respect to purchases in Rhode Island.

y) S.D. Codified Laws §§ 37-1-3.1, et seq., with respect to purchases in South Dakota.

z) Tenn. Code Ann §§ 47-25-101, et seq., with respect to purchases in Tennessee.

aa) Utah Code Ann. §§ 76-10-3101, et seq., with respect to purchases in Utah.

bb) W.Va. Code §§ 47-18-1, et seq., with respect to purchases in West Virginia.

cc) Wis. Stat. §§ 133.01, et seq., with respect to purchases in Wisconsin.

251. HCSC has been injured in their business or property by reason of Jazz and Amneal's violations of the laws set forth above, in that they were, and continue to be: (i) denied the opportunity to purchase lower-priced generic Xyrem; and (ii) paid higher prices for Xyrem than they would have paid but for Jazz and Amneal's unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes Jazz and Amneal's conduct unlawful.

252. HCSC seeks damages and multiple damages as permitted by law.

**COUNT III**

**CONSPIRACY AND COMBINATION IN RESTRAINT OF TRADE UNDER STATE LAW**

(AGAINST JAZZ AND LUPIN)

253. HCSC incorporates by reference the preceding allegations.

254. Jazz and Lupin entered into an agreement or combination in restraint of trade in violation of many states' laws. Jazz and Lupin engaged in a continuing contract, combination, or conspiracy with respect to the sale of Xyrem in unreasonable restraint of trade and commerce, in violation of the various state antitrust statutes set forth below.

255. Jazz and Lupin entered into an unlawful reverse payment agreement that restrained, and continues to restrain, competition in the market for Xyrem and/or its AB-rated generic equivalents.

256. Jazz and Lupin's acts and combinations in furtherance of the conspiracy have caused unreasonable restraints in the market for Xyrem and/or its AB-rated generic equivalents.

257. As a result of Jazz and Lupin's unlawful conduct, Plaintiff has been harmed by being forced to pay artificially inflated, supracompetitive prices for Xyrem.

258. In formulating and carrying out the alleged agreement, understanding, contract, combination and conspiracy, Jazz and Lupin did those things that they combined and conspired to do, including but not limited to the acts, practices, and course of conduct set forth herein.

259. Jazz and Lupin's conspiracy had the following effects, among others: the reverse payment agreement between Jazz and Lupin delayed generic entry and its attendant lower prices for

Plaintiff, and the market allocation output restriction agreement effectively fixed prices at an artificially high level.

260. Jazz and Lupin engaged in the actions described above for the purpose of carrying out their unlawful agreements to fix, raise, maintain, or stabilize prices of Xyrem.

261. There was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on HCSC and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve the purpose. Accordingly, these acts constitute violations of the antitrust laws of various states in accordance with *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

262. By engaging the foregoing conduct, Jazz and Lupin intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of the following state antitrust laws:

a) Arizona Rev. Stat. §§ 44-1401, et seq., with respect to purchases in Arizona.

b) Cal. Bus. & Prof. Code §§ 16700, et seq., with respect to purchases in California.

c) C.G.S.A. §§ 35-26 and 28, et seq., with respect to purchases in Connecticut.

d) D.C. Code §§ 28-4501, et seq., with respect to purchases in the District of Columbia.

e) Haw. Rev. Stat. §§ 480-1, et seq., with respect to purchases in Hawaii.

f) 740 Ill. Comp. Stat. 10/1, et seq., with respect to purchases in Illinois.

g) Iowa Code § 553.1, et seq., with respect to purchases in Iowa.

h) Kan. Stat. Ann. § 50-101, et seq., with respect to purchases in Kansas.

i) Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to purchases in Maine.

j) MD Code Ann., Com. Law, §§ 11-204, et seq., with respect to purchases in Maryland.

k) Mass. Gen. Laws ch. 93A, §§ 1 et seq., with respect to purchases in Massachusetts.

l) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases in Michigan.

m) Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. §§ 8.31, et seq., with respect to purchases in Minnesota.

n) Miss. Code Ann. §§ 75-21-1, et seq., with respect to purchases in Mississippi.

o) Neb. Rev. Stat. Ann. §§ 59-801, et seq., with respect to purchases in Nebraska.

p) Nev. Rev. Stat. Ann. §§ 598A.010, et seq., with respect to purchases in Nevada.

q) N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to purchases in New Hampshire.

r) N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases in New Mexico.

s) N.Y. Gen. Bus. Law § 340, et seq., with respect to purchases in New York.

t) N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases in North Carolina.

u) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases in North Dakota.

v) Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases in Oregon.

w) P.R. Laws Ann. tit. 10 §§ 258, et seq., with respect to purchases in Puerto Rico.

x) R.I. Gen. Laws §§ 6-36-1 et seq., with respect to purchases in Rhode Island.

y) S.D. Codified Laws §§ 37-1-3.1, et seq., with respect to purchases in South Dakota.

z) Tenn. Code Ann §§ 47-25-101, et seq., with respect to purchases in Tennessee.

aa) Utah Code Ann. §§ 76-10-3101, et seq., with respect to purchases in Utah.

bb) W.Va. Code §§ 47-18-1, et seq., with respect to purchases in West Virginia.

cc) Wis. Stat. §§ 133.01, et seq., with respect to purchases in Wisconsin.

263. HCSC has been injured in their business or property by reason of Jazz and Lupin's violations of the laws set forth above, in that they were, and continue to be: (i) denied the opportunity to purchase lower-priced generic Xyrem; and (ii) paid higher prices for Xyrem than they would have paid but for Jazz and Lupin's unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes Jazz and Lupin's conduct unlawful.

264. HCSC seeks damages and multiple damages as permitted by law.

**COUNT IV**

**CONSPIRACY AND COMBINATION IN RESTRAINT OF TRADE UNDER STATE LAW**

(AGAINST JAZZ AND PAR)

265. HCSC incorporates by reference the preceding allegations.

266. Jazz and Par entered into an agreement or combination in restraint of trade in violation of many states' laws. Jazz and Par engaged in a continuing contract, combination, or conspiracy with

respect to the sale of Xyrem in unreasonable restraint of trade and commerce, in violation of the various state antitrust statutes set forth below.

267. Jazz and Par entered into an unlawful reverse payment agreement that restrained, and continues to restrain, competition in the market for Xyrem and/or its AB-rated generic equivalents.

268. Jazz and Par's acts and combinations in furtherance of the conspiracy have caused unreasonable restraints in the market for Xyrem and/or its AB-rated generic equivalents.

269. As a result of Jazz and Par's unlawful conduct, HCSC has been harmed by being forced to pay artificially inflated, supracompetitive prices for Xyrem.

270. In formulating and carrying out the alleged agreement, understanding, contract, combination and conspiracy, Jazz and Par did those things that they combined and conspired to do, including but not limited to the acts, practices, and course of conduct set forth herein.

271. Jazz and Par's conspiracy had the following effects, among others: the reverse payment agreement between Jazz and Par delayed generic entry and its attendant lower prices for HCSC, and the market allocation output restriction agreement effectively fixed prices at an artificially high level.

272. Jazz and Par engaged in the actions described above for the purpose of carrying out their unlawful agreements to fix, raise, maintain, or stabilize prices of Xyrem.

273. There was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on HCSC and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve the purpose. Accordingly, these acts constitute violations of the antitrust laws of various states in accordance with *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

274. By engaging the foregoing conduct, Jazz and Par intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of the following state antitrust laws:

a) Arizona Rev. Stat. §§ 44-1401, et seq., with respect to purchases in Arizona.

b) Cal. Bus. & Prof. Code §§ 16700, et seq., with respect to purchases in California.

c) C.G.S.A. §§ 35-26 and 28, et seq., with respect to purchases in Connecticut.

d) D.C. Code §§ 28-4501, et seq., with respect to purchases in the District of Columbia.

e) Haw. Rev. Stat. §§ 480-1, et seq., with respect to purchases in Hawaii.

f) 740 Ill. Comp. Stat. 10/1, et seq., with respect to purchases in Illinois.

g) Iowa Code § 553.1, et seq., with respect to purchases in Iowa.

h) Kan. Stat. Ann. § 50-101, et seq., with respect to purchases in Kansas.

i) Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to purchases in Maine.

j) MD Code Ann., Com. Law, §§ 11-204, et seq., with respect to purchases in Maryland.

k) Mass. Gen. Laws ch. 93A, §§ 1 et seq., with respect to purchases in Massachusetts.

l) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases in Michigan.

m) Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. §§ 8.31, et seq., with respect to purchases in Minnesota.

n) Miss. Code Ann. §§ 75-21-1, et seq., with respect to purchases in Mississippi.

o) Neb. Rev. Stat. Ann. §§ 59-801, et seq., with respect to purchases in Nebraska.

p) Nev. Rev. Stat. Ann. §§ 598A.010, et seq., with respect to purchases in Nevada.

q) N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to purchases in New Hampshire.

r) N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases in New Mexico.

s) N.Y. Gen. Bus. Law § 340, et seq., with respect to purchases in New York.

t) N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases in North Carolina.

u) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases in North Dakota.

v) Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases in Oregon.

w) P.R. Laws Ann. tit. 10 §§ 258, et seq., with respect to purchases in Puerto Rico.

x) R.I. Gen. Laws §§ 6-36-1 et seq., with respect to purchases in Rhode Island.

y) S.D. Codified Laws §§ 37-1-3.1, et seq., with respect to purchases in South Dakota.

z) Tenn. Code Ann §§ 47-25-101, et seq., with respect to purchases in Tennessee.

aa) Utah Code Ann. §§ 76-10-3101, et seq., with respect to purchases in Utah.

bb) W.Va. Code §§ 47-18-1, et seq., with respect to purchases in West Virginia.

cc) Wis. Stat. §§ 133.01, et seq., with respect to purchases in Wisconsin.

275. Plaintiff has been injured in their business or property by reason of Jazz and Par's violations of the laws set forth above, in that they were, and continue to be: (i) denied the opportunity to purchase lower-priced generic Xyrem; and (ii) paid higher prices for Xyrem than they would have paid but for Jazz and Par's unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes Jazz and Par's conduct unlawful.

276. HCSC seeks damages and multiple damages as permitted by law.

**COUNT V**

**CONSPIRACY AND COMBINATION IN RESTRAINT OF TRADE UNDER STATE LAW**

(AGAINST ALL DEFENDANTS)

277. HCSC incorporates by reference the preceding allegations.

278. Defendants entered into an agreement or combination in restraint of trade in violation of many states' laws. Defendants engaged in a continuing contract, combination, or conspiracy with respect to the sale of Xyrem in unreasonable restraint of trade and commerce, in violation of the various state antitrust statutes set forth below.

279. During the Relevant Period, Defendants entered into an unlawful reverse payment agreement that restrained, and continues to restrain, competition in the market for Xyrem and/or its AB-rated generic equivalents.

280. Defendants' acts and combinations in furtherance of the conspiracy have caused unreasonable restraints in the market for Xyrem and/or its AB-rated generic equivalents.

281. As a result of Defendants' unlawful conduct, HCSC has been harmed by being forced to pay artificially inflated, supracompetitive prices for Xyrem.

282. In formulating and carrying out the alleged agreement, understanding, contract, combination and conspiracy, Defendants did those things that they combined and conspired to do, including but not limited to the acts, practices, and course of conduct set forth herein.

283. Defendants' conspiracy had the following effects, among others:

a) It delayed and continues to delay generic entry of Xyrem in order to lengthen the period in which Jazz's brand Xyrem could and can monopolize the market and make supracompetitive profits;

b) It will keep an authorized generic from Jazz off the market during Hikma's 180-day generic exclusivity period, thereby allowing Hikma to monopolize the generic market for Xyrem during the period, and allowing Hikma to make supracompetitive profits;

c) It will, after Hikma's exclusivity period ends, continue to keep an authorized product from Jazz off the market as Amneal, Lupin, and Par enter with "very limited" quantities (throttled by Jazz) of generic Xyrem; and

d) It raised and maintained the prices that HCSC would and will pay for Xyrem at supracompetitive levels.

284. From January 2023 until at least December 31, 2025, Jazz will share its monopoly power with Hikma, Amneal, Lupin, and Par, and the companies will jointly maintain an illegal monopoly throughout that time.

285. Defendants engaged in the actions described above for the purpose of carrying out their unlawful agreements to fix, raise, maintain, or stabilize prices of Xyrem.

286. There was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on HCSC and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve the purpose. Accordingly, these acts constitute violations of the antitrust laws of various states in accordance with *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

287. By engaging the foregoing conduct, Defendants intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of the following state antitrust laws:

a) Arizona Rev. Stat. §§ 44-1401, et seq., with respect to purchases in Arizona.

b) Cal. Bus. & Prof. Code §§ 16700, et seq., with respect to purchases in California.

c) C.G.S.A. §§ 35-26 and 28, et seq., with respect to purchases in Connecticut.

d) D.C. Code §§ 28-4501, et seq., with respect to purchases in the District of Columbia.

e) Haw. Rev. Stat. §§ 480-1, et seq., with respect to purchases in Hawaii.

f) 740 Ill. Comp. Stat. 10/1, et seq., with respect to purchases in Illinois.

g) Iowa Code § 553.1, et seq., with respect to purchases in Iowa.

h) Kan. Stat. Ann. § 50-101, et seq., with respect to purchases in Kansas.

i) Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to purchases in Maine.

j) MD Code Ann., Com. Law, §§ 11-204, et seq., with respect to purchases in Maryland.

k) Mass. Gen. Laws ch. 93A, §§ 1 et seq., with respect to purchases in Massachusetts

l) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases in Michigan.

m) Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. §§ 8.31, et seq., with respect to purchases in Minnesota.

n) Miss. Code Ann. §§ 75-21-1, et seq., with respect to purchases in Mississippi.

o) Neb. Rev. Stat. Ann. §§ 59-801, et seq., with respect to purchases in Nebraska.

p) Nev. Rev. Stat. Ann. §§ 598A.010, et seq., with respect to purchases in Nevada.

q) N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to purchases in New Hampshire.

r) N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases in New Mexico.

s) N.Y. Gen. Bus. Law § 340, et seq., with respect to purchases in New York.

t) N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases in North Carolina.

u) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases in North Dakota.

v) Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases in Oregon.

w) P.R. Laws Ann. tit. 10 §§ 258, et seq., with respect to purchases in Puerto Rico.

x) R.I. Gen. Laws §§ 6-36-1 et seq., with respect to purchases in Rhode Island.

y) S.D. Codified Laws §§ 37-1-3.1, et seq., with respect to purchases in South Dakota.

z) Tenn. Code Ann §§ 47-25-101, et seq., with respect to purchases in Tennessee.

aa) Utah Code Ann. §§ 76-10-3101, et seq., with respect to purchases in Utah.

bb) W.Va. Code §§ 47-18-1, et seq., with respect to purchases in West Virginia.

cc) Wis. Stat. §§ 133.01, et seq., with respect to purchases in Wisconsin.

288. HCSC has been injured in their business or property by reason of Defendants' violations of the laws set forth above, in that they were, and continue to be: (i) denied the opportunity to purchase lower-priced generic Xyrem; and (ii) paid higher prices for Xyrem than they would have paid but for

Defendants' unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes Defendants' conduct unlawful.

289. HCSC seeks damages and multiple damages as permitted by law.

**COUNT VI**

**MONOPOLIZATION AND MONOPOLISTIC SCHEME UNDER STATE LAW**

(AGAINST JAZZ)

290. HCSC incorporates by reference the preceding allegations.

291. The relevant market is sodium oxybate (Xyrem, Xywav, and Xyrem's AB-rated generic equivalents).

292. As described above, before January 2023, Jazz has maintained and will maintain its monopoly power in the relevant market and, after that point, will share its monopoly power with Hikma first, followed by Amneal, Lupin, and Par, in an illegal monopoly.

293. Jazz willfully and unlawfully engaged in continuing illegal conduct to monopolize the relevant market through at least December 31, 2025 by engaging in an anticompetitive scheme to keep AB-rated generic equivalents of Xyrem from the market—not as a result of providing a superior product, business acumen, or historical accident.

294. Jazz knowingly and intentionally maintained and enhanced its monopoly power in the relevant market, as described herein, injuring HCSC. Jazz accomplished this scheme by:

a) Delaying generic entry of Xyrem in order to lengthen the period in which Jazz's brand Xyrem could monopolize the market and make supra- competitive profits;

b) Keeping an authorized generic off the market during Hikma's 180-day generic exclusivity period, and, subsequently when Amneal, Lupin, and Par are permitted to enter with only limited quantities of generic Xyrem, through at least December 31, 2025, thereby allowing Defendants to monopolize the generic market for Xyrem during the period, and allowing Defendants to make supracompetitive profits;

c) Raising and maintaining the prices so that HCSC would pay supracompetitive prices for Xyrem; and

d) Otherwise conspiring with the other Defendants to unlawfully monopolize the relevant market, including through the use of anticompetitive "acceleration" clauses.

295. The goal, purpose, and effect of Jazz's scheme was also to maintain and extend its monopoly power with respect to Xyrem. Jazz's illegal scheme allowed it to continue charging supracompetitive prices for Xyrem, without a substantial loss of sales, reaping substantial unlawful monopoly profits. Jazz's scheme will allow Hikma to reap the benefits of reduced generic competition in the United States.

296. There is and was no legitimate, non-pretextual, procompetitive justification for Jazz's conduct that outweighs its harmful effects. Even if there were some conceivable justification, the conduct is and was broader than necessary to achieve such a purpose.

297. As a result of Jazz's illegal conduct, HCSC was compelled to pay (and did pay) and continues to be compelled to pay (and does pay), more than it would have paid for Xyrem and/or its generic Xyrem absent Defendants' unlawful conduct. But for Jazz's unlawful conduct, competitors would have begun selling generic Xyrem sooner, and prices paid for the drug or its generic equivalents, would therefore, be less.

298. Had manufacturers of generic Xyrem entered the market and lawfully competed with Jazz (and one another) in a timely fashion, HCSC would have substituted lower-priced generic Xyrem for the higher-priced brand-name Xyrem for some or all of their Xyrem requirements, and/or would have paid lower net prices on their remaining Xyrem and generic Xyrem purchases.

299. But for Jazz's illegal conduct, competitors would have begun marketing generic versions of Xyrem well before January 2023, and they would be able to market such versions successfully.

300. By engaging in the foregoing conduct, Jazz intentionally, willfully, and wrongfully monopolized the relevant market in violation of the following state laws:

a) Arizona Rev. Stat. §§ 44-1403, et seq., with respect to purchases in Arizona.

b) Cal. Bus. & Prof. Code §§ 16700, with respect to purchases in California.

c) C.G.S.A. §§ 35-27, et seq., with respect to purchases in Connecticut.

d) D.C. Code §§ 28-4503, et seq., with respect to purchases in the District of Columbia.

e) Fla. Stat. §§ 501.201, et seq., with respect to purchases in Florida.

f) Haw. Rev. Stat. §§ 480-2, 480-9, et seq., with respect to purchases in Hawaii.

g) 740 Ill. Comp. Stat. 10/1, et seq., with respect to purchases in Illinois.

h) Iowa Code § 553.5, et seq., with respect to purchases in Iowa.

i) Kan. Stat. Ann. § 50-101, et seq., with respect to purchases in Kansas.

j) Me. Rev. Stat. Ann. 10, §§ 1102, et seq., with respect to purchases in Maine.

k) MD Code Ann., Com. Law, §§ 11-204, et seq., with respect to purchases in Maryland.

l) Mass. Gen. Laws ch. 93A, §§ 1 et seq., with respect to purchases in Massachusetts.

m) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases in Michigan.

n) Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. §§ 8.31, et seq., with respect to purchases in Minnesota.

o) Miss. Code Ann. §§ 75-21-3, et seq., with respect to purchases in Mississippi.

p) Mo. Rev. Stat. §§ 407.020, et seq., with respect to purchases in Missouri.

q) Mont. Code Ann. §§ 30-14-101, et seq., with respect to purchases in Montana.

r) Neb. Rev. Stat. Ann. §§ 59-802, et seq., with respect to purchases in Nebraska.

s) Nev. Rev. Stat. Ann. §§ 598A.060, et seq., with respect to purchases in Nevada.

t) N.H. Rev. Stat. Ann. §§ 356.1, et seq., with respect to purchases in New Hampshire.

u) N.M. Stat. Ann. §§ 57-1-2, et seq., with respect to purchases in New Mexico.

v) N.Y. Gen. Bus. Law § 340, et seq., with respect to purchases in New York.

w) N.C. Gen. Stat. §§ 75-2.1, et seq., with respect to purchases in North Carolina.

x) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases in North Dakota.

y) Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases in Oregon.

z) P.R. Laws Ann. tit. 10, §§ 260, et seq., with respect to purchases in Puerto Rico.

aa) R.I. Gen. Laws §§ 6-36-5 et seq., with respect to purchases in Rhode Island.

bb) S.D. Codified Laws §§ 37-1-3.2, et seq., with respect to purchases in South Dakota.

cc) Tenn. Code Ann §§ 47-25-101, et seq., with respect to purchases in Tennessee.

dd) Utah Code Ann. §§ 76-10-3101, et seq., with respect to purchases in Utah.

ee) Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases in Vermont.

ff) W.Va. Code §§ 47-18-1, et seq., with respect to purchases in West Virginia.

gg) Wis. Stat. §§ 133.03, et seq., with respect to purchases in Wisconsin.

301. HCSC has been injured in their business or property by reason of Jazz's violations of the laws set forth above, in that they were, and continue to be: (i) denied the opportunity to purchase lower-priced generic Xyrem; and (ii) paid higher prices for Xyrem than they would have paid but for Jazz's unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes Jazz's conduct unlawful.

302. HCSC seeks damages and multiple damages as permitted by law.

**COUNT VII**

**FOR DECLARATORY AND INJUNCTIVE RELIEF FOR VIOLATIONS OF SECTION 16 OF THE CLAYTON ACT, 15 U.S.C. §§ 1-2, 26)**

(AGAINST ALL DEFENDANTS)

303. HCSC incorporates by reference the preceding allegations.

304. HCSC seeks declaratory and injunctive relief under state antitrust laws.

305. As set forth above, Defendants have violated Section 16 of the Clayton Act, 15 U.S.C. § 26.

306. HCSC has been injured in its business or property by reason of Defendants' antitrust violations. This injury consists of paying higher prices for Xyrem than HCSC would have paid in the absence of those violations. These injuries will continue unless halted.

307. HCSC, pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable laws, hereby seeks a declaratory judgment to correct the anticompetitive effects caused by Defendants' unlawful conduct and to restore competition in the market for Xyrem.

**COUNT VIII**

**UNJUST ENRICHMENT UNDER STATE LAW**

**(AGAINST ALL DEFENDANTS)**

308. HCSC incorporates by reference the preceding allegations.

309. Defendants benefitted from monopoly profits on the sale of Xyrem resulting from the unlawful and inequitable acts alleged in this Complaint.

310. Defendants' financial benefit resulting from its unlawful and inequitable acts is traceable to overpayments for Xyrem by HCSC.

311. HCSC has conferred upon Defendants an economic benefit, profits from unlawful overcharges and monopoly profits, to the economic detriment of HCSC.

312. It would be futile for HCSC to seek a remedy from any party with whom they have privity of contract with for its purchases of Xyrem.

313. It would be futile for HCSC to seek to exhaust any remedy against immediate intermediary in the chain of distribution from which it indirectly purchased Xyrem, as they are not liable and would not compensate HCSC for unlawful conduct caused by Defendants.

314. The economic benefit of overcharges and monopoly profits derived by Defendants through charging supracompetitive and artificially inflated prices for Xyrem is a direct and proximate result of Defendants' unlawful conduct.

315. The economic benefits derived by Defendants rightfully belong to HCSC, as it paid anticompetitive and monopolistic prices between as early as July 17. 2017 and the present, benefiting Defendants.

316. It would be inequitable under unjust enrichment principles under the law of the District of Columbia and the laws of all states and territories in the United States for Defendants to be permitted to retain any of the overcharges for Xyrem derived from Defendants' unfair and unconscionable methods, acts, and trade practices alleged in this Complaint. HCSC asserts claims under all such states' laws.

317. Defendants are aware of and appreciates the benefits bestowed upon them by Plaintiff.

318. Defendants should be compelled to disgorge in a common fund for the benefit of Plaintiff all unlawful or inequitable proceeds they received.

319. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to HCSC.

## XII. DEMAND FOR JUDGMENT

WHEREFORE, HCSC prays for judgment against Defendants and for the following relief:

A. A declaration that the conduct alleged in this Complaint is in violation of the law, including each of the laws asserted in this Complaint;

B. An award of HCSC's overcharge damages, in an amount to be proven and determined at trial, trebled as provided by law; with pre- and post-judgment interest at the statutory rates;

C. An award to HCSC of equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;

D. An award to HCSC of reasonable costs and expenses, including attorneys' fees; and

E. An award of all other legal or equitable relief as the Court deems just and proper.

## XIII. JURY DEMAND

HCSC demands a jury trial on all claims so triable under Federal Rule of Civil Procedure 38(b).

DATED: February 17, 2022

**SCHNEIDER WALLACE COTTRELL KONECKY LLP**

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